In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

Filed: October 22, 2021

DONALD A. HAUBNER,	*	No. 16-1426V
Petitioner,	*	Special Master Sanders
v.	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	Decision; Entitlement; Ruling on the Record; Influenza ("Flu") Vaccine; Peripheral Neuropathy
Respondent.	*	

Andrew D. Downing, Van Cott & Talamante, PLLC, Phoenix, AZ, for Petitioner.
Daniel A. Principato, United States Department of Justice, Washington, DC, for Respondent.

DECISION[1]

On October 28, 2016, Donald A. Haubner ("Petitioner") filed a petition for compensation in the National Vaccine Injury Compensation Program ("the Program").[2] ECF No. 1. Petitioner alleged that the influenza ("flu") vaccine he received on October 30, 2013,[3] caused him to suffer

[1] This Decision shall be posted on the United States Court of Federal Claims' website, in accordance with the E-Government Act of 2002, 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). **This means the Decision will be available to anyone with access to the Internet**. In accordance with Vaccine Rule 18(b), a party has 14 days to identify and move to delete medical or other information that satisfies the criteria in § 300aa-12(d)(4)(B). Further, consistent with the rule requirement, a motion for redaction must include a proposed redacted Decision. If, upon review, the undersigned agrees that the identified material fits within the requirements of that provision, such material will be deleted from public access.

[2] National Childhood Vaccine Injury Act of 1986, Pub L. No. 99-660, 100 Stat. 3755 ("the Vaccine Act" or "Act"). Hereinafter, for ease of citation, all "§" references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

[3] Petitioner's medical records indicate that the vaccine was administered on October 29, 2013. Pet'r's Ex. 8 at 3, ECF No. 16-1. Petitioner later submitted a status report and response to Respondent's Rule 4(c) report in which he claimed that the October 29, 2013 date was incorrect and that he instead received the vaccine on October 30, 2013. *See* ECF No. 42-1 at 3. Due to inconsistencies in the page numbering in ECF No. 42-1, this citation and all further citations to this document refer to the numbers generated by CM/ECF.

from peripheral neuropathy.[4] [5]*Id.* at 1. For the reasons discussed herein, I find that Petitioner is not entitled to compensation.

I. Procedural History

Petitioner filed his petition, affidavit, and several medical records on October 28, 2016. ECF No. 1. Petitioner submitted additional medical records on November 10, 2016, and a statement of completion on November 29, 2016. ECF Nos. 7–8. This case was reassigned to me on January 13, 2017. ECF Nos. 12–13. Petitioner filed outstanding medical records on June 1, 2017, June 9, 2017, and August 15, 2017. ECF Nos. 16, 18, 22.

I held a telephonic status conference with counsel for the parties on August 16, 2017. Min. Entry, docketed Aug. 16, 2017; Order at 1, ECF No. 23. During the status conference, I identified a potential onset issue and advised Petitioner to ask any future expert to analyze it. Order at 2. I also "stressed the need for Petitioner to ensure that the medical records necessary to prove his case are obtained and filed." *Id.* at 1. Petitioner filed additional medical records on September 13, 2017 and November 15, 2017. ECF Nos. 26, 29. He filed his amended statement of completion on the latter date. ECF No. 30.

Respondent filed his Rule 4(c) report on December 15, 2017. Resp't's Report, ECF No. 31. Respondent stated that "compensation is not appropriate in this case." *Id.* at 1. Respondent argued that "the record fails to establish a causal connection between [P]etitioner's flu vaccine and any of his conditions." *Id.* at 7. Respondent asserted that the record contains "evidence that all of [P]etitioner's conditions preexisted his vaccination." *Id.* He continued that Petitioner had not established that his claims meet the requirements to establish causation-in-fact or significant aggravation. *See id.* at 7–8.

Petitioner's counsel withdrew on February 7, 2018. *See* ECF Nos. 32, 34–35. Following multiple delays and communications with Petitioner, I ordered Petitioner to file additional medical records and have an attorney file a motion to enter as counsel by April 16, 2018. *See* ECF Nos. 38, 40; Informal Comms., docketed Feb. 22, 2018, Feb. 23, 2018, Mar. 1, 2018, and Mar. 26, 2018.

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[4] Neuropathy is "a functional disturbance or pathologic change in the peripheral nervous system, sometimes limited to noninflammatory lesions as opposed to those of neuritis; the etiology may be known or unknown. Known etiologies include complications of other diseases (such as diabetes or porphyria), or of toxicity states [ ]." *Neuropathy*, DORLAND'S MEDICAL DICTIONARY ONLINE [hereinafter "DORLAND'S"], https://www.dorlandsonline.com (last visited July 9, 2021). The peripheral nervous system is "the part of the nervous system consisting of nerves and ganglia outside the brain and spinal cord." *Peripheral Nervous System*, DORLAND'S, https://www.dorlandsonline.com (last visited July 9, 2021).

[5] Petitioner also alleged that his vaccination caused his carpal tunnel syndrome ("CTS") and hypothyroidism. These allegations are not supported by the record, and Petitioner did not continue to argue, or attempt to provide support for, the argument that his vaccination caused these conditions. Thus, I will not consider whether Petitioner is entitled to compensation for his CTS or hypothyroidism. CTS is "an entrapment neuropathy characterized by pain and burning or tingling paresthesias in the fingers and hand, sometimes extending to the elbow." Carpal Tunnel Syndrome, DORLAND'S, https://www.dorlandsonline.com (last visited July 9, 2021). Hypothyroidism refers to a "deficiency of thyroid activity, characterized by decrease in basal metabolic rate, fatigue, and lethargy[.]" *Hypothyroidism*, DORLAND'S, https://www.dorlandsonline.com (last visited July 9, 2021).

On April 16, 2018, Petitioner, then acting *pro se*, filed a status report that included various documents. *See* ECF No. 42-1. In his status report, Petitioner attempted to clarify a discrepancy regarding his date of vaccination as well as a statement he made in his affidavit regarding his condition in the days post vaccination. *Id.* at 1–3. Petitioner further included a reply to Respondent's Rule 4(c) report. *Id.* at 4–21. Petitioner's submission also included some medical records and other documents. *See id.* at 22–38.

On May 4, 2018, Petitioner filed a document that included medical records, photographs, and character references, as well as a status update indicating that he was speaking with another attorney about representation. ECF No. 45 at 4. Petitioner filed a status report on May 23, 2018 and stated he would proceed *pro se*. ECF No. 48 at 1.

On June 4, 2018, I ordered Petitioner to file an expert report by August 6, 2018. Order at 1, ECF No. 49. Petitioner contacted Chambers on June 21, 2018, requesting sixty additional days to file an expert report and to allow an attorney to file a motion to substitute counsel. Informal Comm., docketed June 21, 2018; Order, ECF No. 51. Petitioner informed Chambers that he had retained an expert. ECF No. 51. I granted Petitioner's request. *Id.*

Petitioner's current counsel filed a motion to substitute attorney on August 15, 2018. ECF No. 52. After Petitioner missed his deadline to submit his expert report, I ordered him to file it by October 16, 2018. Sched. Order, docketed Aug. 22, 2018. Petitioner was unable to produce his expert report over the following months. *See* ECF Nos. 54, 56, 59, 61, 64.

On February 6, 2019, Petitioner filed a "record review and report" from Aaron Haubner, Ph.D., and a letter from Petitioner's treating neurologist, P. Scott Becker, M.D. *See* ECF No. 66. Petitioner also filed a letter from his primary care physician ("PCP"), Robert Tracy, M.D., on February 11, 2019, and an additional letter from Dr. Becker on February 25, 2019. ECF Nos. 70–71. Petitioner filed his November 2013 work schedule on March 7, 2019. ECF No. 73.

On March 8, 2019, Petitioner submitted a status report indicating that he wished for a ruling on the record. ECF No. 74 at 1. On April 9, 2019, I ordered Respondent to submit a responsive expert report. Sched. Order, docketed Apr. 9, 2019. Respondent filed two expert reports on August 9, 2019. ECF Nos. 77–79. I ordered Petitioner to file his motion for a ruling on a record and supportive brief by October 15, 2019. Sched. Order, docketed Aug. 16, 2019. Respondent proceeded to file medical literature on September 17, 2019. ECF Nos. 80–82.

On October 15, 2019, Petitioner filed his motion for a ruling on the record and medical literature. ECF No. 83; Pet'r's Mot., ECF No. 84. Respondent filed his response on December 16, 2019. Resp't's Resp., ECF No. 85. Petitioner followed with a reply on January 15, 2020. Pet'r's Reply, ECF No. 86.

I have determined that a ruling on the record is appropriate in this case. Petitioner requested a ruling on the record. Further, Petitioner has had the opportunity to submit expert reports and other evidence in support of his claim.

This matter is now ripe for consideration.

II. Evidence

A. Relevant Medical History

1. Pre-vaccination Medical History

Petitioner was born on January 22, 1963. *E.g.*, Pet'r's Ex. 2 at 1, ECF No. 1-3. His pre-vaccination medical history is notable for restless legs syndrome,[6] migraine headaches, insomnia, anxiety, chronic pain in various areas, bilateral carpel tunnel syndrome ("CTS"), bilateral ulnar neuropathy,[7] cervical degenerative disc disease, [8] osteoarthritis ("OA"), hypertension, elevated cholesterol readings, obesity, and allergic rhinitis. *See generally* Pet'r's Ex. 2.

During an appointment with Dr. Tracy on April 10, 2012, Petitioner reported pain in his "back, left knee, right knee, and left hand." Pet'r's Ex. 2 at 116. On a scale of 1 to 10, Petitioner rated his pain as an 8/10. *Id.* Dr. Tracy noted that "[t]his is a chronic problem. The current episode started more than [one] year ago. There has been no history of extremity trauma. The problem occurs constantly . . . Associated symptoms include joint locking, joint swelling, and a limited range of motion." *Id.* On November 10, 2012, Petitioner presented to the after-hours clinic at Commonwealth Orthopaedic Centers reporting right ankle pain. Pet'r's Ex. 4 at 9, ECF No. 1-5. Petitioner reported a "history of lower extremity issues due to a . . . leg length discrepancy . . . that has required the use of . . . a built-up shoe [and] orthotics[]" but that he had not made recent changes to his orthotics and could not recall a triggering incident. *Id.* Petitioner noted pain with any weightbearing. *Id.* The provider assessed Petitioner with possible peroneus tendonitis[9] but expressed concern that his "exquisite pain" when weightbearing was "unlike typical tendonitis[.]" *Id.*

During a December 4, 2012 visit to Dr. Tracy's office, Petitioner followed up regarding his chronic pain. Pet'r's Ex. 2 at 114. The locations of the pain are listed as "back - lower, foot - bilateral, hip - bilateral, and knee - bilateral." *Id.* Petitioner did not indicate any functional

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[6] Restless legs syndrome refers to "unpleasant deep discomfort including paresthesias inside the calves when sitting or lying down, especially just before sleep, producing an irresistible urge to move the legs[.]" *Restless Legs Syndrome*, DORLAND'S, https://www.dorlandsonline.com (last visited July 9, 2021).

[7] Ulnar neuropathy refers to neuropathy of the ulnar nerve. "Those in the elbow region are usually entrapment neuropathies [ ]; those in the wrist region may cause only muscle weakness in the hand or weakness accompanied by sensory deficits in the areas of the little finger." *Ulnar Neuropathy*, DORLAND'S, https://www.dorlandsonline.com (last visited July 9, 2021). The ulnar nerve is distributed through various parts of the hands, forearms, and elbows. *See Nervus Ulnaris*, DORLAND'S, https://www.dorlandsonline.com (last visited July 9, 2021). Entrapment neuropathies are "neuropathies, often overuse injuries, in which a peripheral nerve is injured by compression in its course through a fibrous or osseofibrous tunnel or at a point where it abruptly changes its course through deep fascia over a fibrous or muscular band." *Entrapment Neuropathy*, DORLAND'S, https://www.dorlandsonline.com (last visited July 9, 2021).

[8] Cervical "pertain[s] to the neck[]" or "to the neck or cervix of any organ or structure." *Cervical*, DORLAND'S, https://www.dorlandsonline.com (last visited Aug. 11, 2021). Spondylosis, or degenerative disc disease, refers to "ankylosis of a vertebral joint[]" and "degenerative spinal changes due to osteoarthritis." *Spondylosis*, DORLAND'S, https://www.dorlandsonline.com (last visited Sept. 8, 2021). Ankylosis is "immobility and consolidation of a joint . . . ." *Ankylosis*, DORLAND'S, https://www.dorlandsonline.com (last visited Sept. 8, 2021).

[9] Tendonitis, or tendinitis, is "inflammation of tendons and of tendon-muscle attachments[.]" *Tendinitis*, DORLAND'S, https://www.dorlandsonline.com (last visited July 9, 2021). Peroneous related to the leg. *See Peroneal*, DORLAND'S, https://www.dorlandsonline.com (last visited July 9, 2021).

limitations. *See id.* Petitioner returned to Dr. Tracy for another chronic pain follow-up on February 28, 2013. *Id.* at 105. The locations of pain are listed as "knee - bilateral and thumb - left." Petitioner rated his pain as ranging from a 2/10 to a 6/10 and did not report functional limitations. *Id.* Dr. Tracy noted that Petitioner was "positive for arthralgias[10] and stiff joints, hyperextended his right thumb when he fell." *Id.*

On April 2, 2013, Petitioner returned to Dr. Tracy complaining of pain in his right wrist. *Id.* at 103. Petitioner stated that this pain, which he rated as a 10/10, began eight weeks before, after he fell on said wrist. *Id.* at 103. Dr. Tracy noted that Petitioner was positive for fatigue as well as arthralgias, back pain, and bone pain. *Id.*

On April 19, 2013, Petitioner presented to Dr. Thomas Due at St. Elizabeth Healthcare. Pet'r's Ex. 3 at 23, ECF No. 1-4. Dr. Due noted that Petitioner's EMGs showed "bilateral carpal tunnel syndrome and possibly a diffuse demyelinating[11] ulnar neuropathy without obvious compression." *Id.* Dr. Due continued that Petitioner "mostly ha[d] carpal tunnel symptoms and pain at the basilar joints of his thumbs." *Id.* Dr. Due and Petitioner discussed various treatment options, including surgery. *Id.*

On April 30, 2013, Petitioner returned to Dr. Tracy for a chronic pain follow-up. Pet'r's Ex. 2 at 100. Petitioner reported "sharp, burning, and continuous[]" pain ranging from a severity of 4/10 to 8/10. *Id.* Functional limitations listed include "[u]nable to complete manual labor, [u]nable to perform tasks required for any employment." *Id.* Dr. Tracy noted that Petitioner was planning wrist surgery. *Id.* A physical exam revealed bilateral hand pain, and Dr. Tracy noted that Petitioner was positive for myalgias. *Id.* at 101. Dr. Due performed bilateral carpal tunnel release surgery on Petitioner on May 2, 2013. Pet'r's Ex. 3 at 24. Petitioner's pre and postoperative diagnoses were listed as bilateral CTS. *Id.*

On August 13, 2013, Petitioner presented to Dr. Tracy complaining of left arm pain for one week. Pet'r's Ex. 2 at 94. Petitioner stated that the pain was intermittent and radiated from his neck to his fingertips. *Id.* Petitioner noted that certain motions of his neck and arm aggravated the pain. *Id.* Dr. Tracy wrote that "[Petitioner] was recently on vacation and playing in the waves and was get [sic] slapped around. No specific trauma. Has had cervical disc disease 15 + years ago." *Id.* Dr. Tracy recommended physical therapy and prescribed methylprednisolone[12] for cervical degenerative joint disease as well as an electrocardiogram[13] test for his arm pain. *Id.* at 96.

On August 22, 2013, Petitioner reported to physical therapist Marci Walicki for an evaluation. Pet'r's Ex. 7 at 32, ECF No. 7-1. PT Walicki wrote that "[Petitioner] reports he has

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[10] Arthralgia is "pain in a joint[.]" *Arthralgia*, DORLAND'S, https://www.dorlandsonline.com (last visited July 9, 2021).

[11] A demyelinating condition is "any condition characterized by destruction of the myelin sheaths of nerves." *Demyelinating Disease*, DORLAND'S, https://www.dorlandsonline.com (last visited July 9, 2021).

[12] Methylprednisolone is "a synthetic glucocorticoid derived from progesterone, used in replacement therapy for adrenocortical insufficiency and as an anti-inflammatory and immunosuppressant . . . ." *Methylprednisolone*, DORLAND'S, https://www.dorlandsonline.com (last visited Sept. 24, 2021).

[13] An electrocardiogram is "a graphic tracing of the variations in the electrical potential caused by the excitation of the heart muscle and detected at the body surface." *Electrocardiogram*, DORLAND'S, https://www.dorlandsonline.com (last visited Sept. 28, 2021).

been having neck pain for [three] weeks. He reports insidious onset of pain. He thinks his pain could have been caused by when he was at the beach and was getting hit by big waves. He states a couple days later he had numbness in left arm to fingers." *Id.* Petitioner reported that his pain had improved since beginning steroid medication but noted difficulty "with driving, reaching, and activities that cause him to move his neck or move his arm up." *Id.* PT Walicki noted that Petitioner had "[i]ntermittent;[a]ching;[s]harp (sharp pains in general have improved)" in his neck, and Petitioner rated his pain as a 2/10. *Id.* Petitioner had numbness and tingling in "left upper extremity to fingers[.]" *Id.* PT Walicki noted that Petitioner's "[l]eft upper trapezius[14] and left cervical paraspinals[15] was [sic] tender to palpation[.]" *Id.* She observed that Petitioner's "[b]ilateral shoulder range of motion was within functional limits." *Id.* at 33. PT Walicki's assessments were "pain;[d]ecreased [range of motion]/flexibility;[d]ecreased strength;[f]unctional limitation;[p]ostural deficits;[and w]ork limitations[.]" *Id.* Petitioner returned for physical therapy on August 27, August 29, September 3, September 5, September 10, September 12, September 17, and September 19, 2013. *Id.* at 50–89.

2. Vaccination and Post-vaccination Medical History

Petitioner's vaccination record indicates that he received his flu vaccine on October 29, 2013, at TriHealth. Pet'r's Ex. 8 at 2–3, ECF No. 16-1. Nine days post vaccination, on November 7, 2013, Petitioner presented to Dr. Tracy complaining of "congestion, myalgias,[16] headache, chills, no appetite and fatigue and nausea for [five] days." Pet'r's Ex. 2 at 90. Dr. Tracy noted that Petitioner had recently received a flu vaccine. *Id.* Petitioner also reported "dull, achy[]" pain in his back, which he rated as ranging from a severity of 3/10 to 9/10. *Id.* at 92. Dr. Tracy's assessments were fatigue and breakthrough pain. *Id.* at 93. Regarding Petitioner's fatigue, Dr. Tracy indicated that he wanted to test Petitioner's thyroid stimulating hormone ("TSH")[17] and vitamin B12 levels and to perform a CBC,[18] comprehensive metabolic panel, and venipuncture. *See id.* at 93. Petitioner's TSH was mildly elevated. *See id.* at 84. Regarding Petitioner's breakthrough pain, Dr. Tracy stated that Petitioner's triggers were working, lifting, and activities of daily living ("ADLs"). *Id.* at 93. He recommended treatment with rest, heat, and PRN[19] medications. *Id.*

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[14] The trapezius muscle "elevates shoulder, rotates scapula to raise shoulder in abduction of arm, draws scapula backward." *Musculus Trapezius*, DORLAND'S, https://www.dorlandsonline.com (last visited Aug. 11, 2021).

[15] Paraspinals "pertain[s] to a plane along the spine." *Paraspinal*, DORLAND'S, https://www.dorlandsonline.com (last visited Aug. 11, 2021).

[16] Myalgias are "pain[s] in a muscle or muscles." *Myalgia*, DORLAND'S, https://www.dorlandsonline.com (last visited Aug. 11, 2021).

[17] Thyroid-stimulating hormone, or thyrotropin, is "a glycoprotein anterior pituitary hormone [] that promotes the growth of, sustains, and stimulates hormonal secretion of the thyroid gland." *Thyrotropin*, DORLAND'S, https://www.dorlandsonline.com (last visited Aug. 11, 2021). The thyroid gland is "an endocrine gland normally situated in the lower part of the front of the neck[] . . . . It secretes, stores, and liberates the thyroid hormones [], which . . . play major endocrine roles in regulating the metabolic rate." *Glandula Thyreoidea*, DORLAND'S, https://www.dorlandsonline.com (last visited Aug. 11, 2021).

[18] A CBC, or complete blood count, is "a series of tests of the peripheral blood[.]" *Complete Blood Count*, DORLAND'S, https://www.dorlandsonline.com (last visited Aug. 11, 2021).

[19] PRN, or pro re nata, refers to medications taken "according to circumstances." *P.R.N.*, DORLAND'S, https://www.dorlandsonline.com (last visited Sept. 28, 2021).

More than four months later, on March 26, 2014, Petitioner visited Dr. Tracy for an annual physical exam. *Id.* at 85. "Diagnoses and associated orders for this visit[]" included, among other things, hypothyroidism, and instructions to take levothyroxine[20] to treat it, "[o]pioid type dependence, continuous[,][21]" and peripheral neuropathy. *Id.* Dr. Tracy noted that, since Petitioner's last visit, Petitioner had visited Dr. Suchoski[22] and that Dr. Suchoski was following Petitioner's peripheral neuropathy. *Id.* at 82, 85.

Petitioner returned to Dr. Tracy on July 21, 2014, for a chronic pain follow-up. *Id.* at 78. Petitioner reported "sharp, throbbing[]" pain in both elbows ranging from a severity of 0/10 to 7/10. *Id.* Dr. Tracy indicated that Petitioner was not experiencing functional limitations. *Id.* Petitioner reported fatigue but was "negative for dizziness, gait problems, headaches and weakness[.]" *Id.* at 79. The physical exam revealed left elbow tenderness over the ulnar nerve and a "[p]ositive [t]inel sign[23] on the left side." *Id.* The neurologic exam was "[g]rossly normal[,]" and the musculoskeletal exam revealed focal pain in the lumbar spine,[24] left elbow, and both hands. *Id.* Diagnoses and orders associated with the appointment included, among others, OA of the hands and elbows, cervical degenerative disc disease, and left ulnar neuropathy. *Id.* at 79–80. Dr. Tracy provided an ambulatory referral for hand surgery for Petitioner's ulnar neuropathy. *Id.* at 80. Triggers for Petitioner's breakthrough pain remained listed as "ADLs, working and lifting[.]" *Id.*

On September 26, 2014, Petitioner presented to Dr. Tracy with complaints of fatigue, joint pain, and a migraine. *Id.* at 74. Petitioner stated that he had been experiencing fatigue "for months[]" and that it had been "getting extremely worse x [one] month." *Id.* Petitioner reported "[a]ll over joint pain off and on for years." *Id.* Petitioner stated that he began experiencing elbow pain six months prior but that Horizant[25] had provided some relief. *Id.* Petitioner also reported

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[20] Levothyroxine sodium is "used as replacement therapy for hypothyroidism and in the prophylaxis and treatment of goiter[, or thyroid gland enlargement] and of thyroid carcinoma[.]" *Levothyroxine Sodium*, DORLAND'S, https://www.dorlandsonline.com (last visited Aug. 5, 2021); *Goiter*, DORLAND'S, https://www.dorlandsonline.com (last visited Aug. 5, 2021).

[21] This appears relate to Petitioner's prescribed use of hydrocodone-acetaminophen to treat his medical conditions. Petitioner's medical records indicate that Petitioner was prescribed this medication since at least 2011. *See* Pet'r's Ex. 2 at 120–121. Hydrocodone is "a semisynthetic opioid analgesic[,]" and acetaminophen is "the amide of acetic acid and p-aminophenol, having analgesic and antipyretic effects similar to those of aspirin but only weak antiinflammatory effects." *Hydrocodone*, DORLAND'S, https://www.dorlandsonline.com (last visited Oct. 20, 2021); *Acetaminophen*, DORLAND'S, https://www.dorlandsonline.com (last visited Oct. 20, 2021).

[22] Petitioner's records from Good Samaritan Hospital refer to a Dr. Suchoski, but it is unclear in the records whether Dr. Suchoski was involved in diagnosing or treating Petitioner's peripheral neuropathy. *See, e.g.*, Pet'r's Ex. 7 at 121, ECF No. 7-1.

[23] A Tinel sign is "a tingling sensation in the distal end of a limb when percussion is made over the site of a divided nerve. It indicates a partial lesion or the beginning regeneration of the nerve." *Tinel Sign*, DORLAND'S, https://www.dorlandsonline.com (last visited July 9, 2021).

[24] The lumbar spine is "the part of the spine comprising the lumbar vertebrae." *Lumbar Spine*, DORLAND'S, https://www.dorlandsonline.com (last visited July 9, 2021).

[25] Horizant is a trademark for gabapentin enacarbil, which is, "a prodrug of gabapentin used in the treatment of restless legs syndrome." *Horizant*, DORLAND'S, https://www.dorlandsonline.com (last visited Aug. 11, 2021); *Gabapentin Enacarbil*, DORLAND'S, https://www.dorlandsonline.com (last visited Aug. 11, 2021). Gabapentin is "an anticonvulsant . . . used as adjunctive therapy in the treatment of partial

"sweat[ing] easily with activities." *Id.* at 75. The diagnoses associated with the appointment were hypothyroidism, fatigue, chest pain, and arthralgia. *Id.* at 76. Dr. Tracy noted that Petitioner's levothyroxine dose had recently increased. *Id.*

Petitioner followed up with Dr. Tracy on October 22, 2014, "for evaluation of possible thyroid disease." *Id.* at 68–69. Petitioner also reported "dull, achy, throbbing[]" pain in his lower back ranging from a 3/10 to a 10/10. *Id.* at 71. Petitioner noted difficulty with some ADLs. Petitioner stated that he "[f]eels his neuropathy is getting progressively worse. Noticing increase [sic] symptoms in his hands and feet. Loosing [sic] fine motor skills." *Id.* A physical exam also revealed focal pain in the elbows and feet. *Id.* at 72. The triggers of Petitioner's breakthrough pain remained the same. *See id.* at 73.

On January 8, 2015, Petitioner presented to neurologist Dr. Becker after being referred by Dr. Tracy in October 2014. Pet'r's Ex. 5 at 37, ECF No. 1-6. Dr. Becker noted that "[s]ince 2011, [Petitioner] had slowly progressive numbness and tingling pains in his arms and hands, greater than the feet. He felt lost [sic] [sixty percent] of the strength in his hands since [June 2014]. The pain in his upper extremities was a [9/10] and the lower extremities a [4/10]." *Id.* Petitioner reported receiving yearly flu shots since 2011 and that he "last year felt 'like dying' for a month afterwards[,]" but Dr. Becker noted "no clear temporal relationship to his symptoms." *Id.* Dr. Becker noted that Petitioner's April 2013 upper extremity EMG/NCV "(only) showed mild bilateral CTS and mild bilateral ulnar neuropathy at the elbow." *Id.* Dr. Becker wrote that Petitioner's bilateral CTS surgery did not result in improvement. *Id.* Dr. Becker noted that Petitioner's blood tests administered on September 26, 2014 and November 4, 2014 checking for various abnormalities and diseases were unremarkable save for his SPEP,[26] which revealed a faint kappa band. *Id.* Dr. Becker stated that a November 17, 2014 "MRI scan of the C-spine showed C3-C4 moderate to severe right and C6-C7 moderate bilateral foraminal narrowing." *Id.* He continued that Petitioner was advised to try cervical traction on November 17, 2014, but did not do so. *Id.* Petitioner reported that he had been taking Horizant at various doses since April 2014. *Id.* Petitioner reported that it "helped 20%" at 900 mg and 60% at 1200 mg. *Id.* Petitioner reported that since changing his dosage to 600 mg on December 11, 2014, "his pain has worsened and the hands are a [12/10] and the feet a [4/10], at times going up to a [12/10]." *Id.* Petitioner noted that he also took gabapentin from October 2014 to December 2014. *Id.* Petitioner also reported adding Cymbalta[27] on that date but that it made his "arms shaky." *Id.* Petitioner also stated that he was taking multi-vitamin injections and "Juice Plus." *Id.* at 38. Dr. Becker stated that Petitioner's "extensive blood work-up was negative, except he declined a [very-long-chain fatty acids[28] test

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seizures and the management of postherpetic neuralgia[.]" *Gabapentin*, DORLAND'S, https://www.dorlandsonline.com (last visited Oct. 21, 2021).

[26] A SPEP is "an assay for the presence of M component in the serum, indicative of plasma cell dyscrasias." *Serum Protein Electrophoresis*, DORLAND'S, https://www.dorlandsonline.com (last visited Sept. 28, 2021).

[27] Cymbalta is a trademark for duloxetine hydrochloride, which is "a serotonin-norepinephrine reuptake inhibitor, used for the treatment of major depressive disorder and the relief of pain in diabetic neuropathy[.]" *Cymbalta*, DORLAND'S, https://www.dorlandsonline.com (last visited Aug. 12, 2021); *Duloxetine Hydrochloride*, DORLAND'S, https://www.dorlandsonline.com (last visited Aug. 12, 2021).

[28] Very-long-chain fatty acids "are oxidized in the peroxisomes and accumulate in the tissues in disorders affecting peroxisome function." *Very-Long-Chain Fatty Acids*, DORLAND'S, https://www.dorlandsonline.com (last visited Sept. 28, 2021).

("VLCFA") and a Charcot-Marie-Tooth disease[29]/ hereditary neuropathy with liability to pressure palsies[30] test ("CMT/HNPP")] due to the cost[.]" *Id.* at 38. Dr. Becker noted that Petitioner planned to have an EMG/CMV of the lower extremities and that Petitioner's April 15, 2013 EMG did not show evidence of radiculopathy. *Id.* Dr. Becker advised Petitioner to taper and discontinue Cymbalta and prescribed Lyrica.[31] *Id.* Dr. Becker also advised that Petitioner make an appointment with a pain clinic and to "get an opinion from Dr. Heile . . . regarding a possible sural nerve[32] biopsy, etc." *Id.*

Petitioner returned to Dr. Becker for a follow-up on February 5, 2015. *Id.* at 33. Petitioner stated that "in retrospect, he feels his symptoms worsened after his flu shot in 2013." *Id.* He also stated that he would proceed with a VLCFA. *Id.* Petitioner reported that since discontinuing Cymbalta and adding Lyrica, "the pain in his hands decreased from a 12 to an [8/10], but the feet are still a [4/10] and at times go up to an [8/10]." *Id.* at 34. Dr. Becker noted that a January 26, 2015 EMG/NCV of Petitioner's lower extremities "showed left, greater than right sensory motor peripheral neuropathy with axonal[33] and demyelinating features with left, greater than right L5 radiculopathy.[34]" *Id.* Dr. Becker stated that he and Petitioner "discussed the possibility of CIDP[35]

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[29] Charcot-Marie-Tooth disease is "a group of hereditary conditions characterized by chronic motor and sensory polyneuropathy of variable inheritance and including autosomal dominant, autosomal recessive, and X-linked forms. . . . All [types] are characterized by progressive symmetric distal muscle weakness and atrophy starting in the feet and legs, gait disturbance, and absent stretch reflexes." *Charcot-Marie-Tooth Disease*, DORLAND'S, https://www.dorlandsonline.com (last visited Sept. 28, 2021).

[30] Hereditary neuropathy with liability to pressure palsies is "an autosomal dominant neuropathy due to deletion of the *PMP22* gene [], which encodes a specific myelin protein[.]" *Hereditary Neuropathy with Liability to Pressure Palsies*, DORLAND'S, https://www.dorlandsonline.com (last visited Sept. 28, 2021).

[31] Lyrica is a trademark for pregabalin, which is "a derivative of γ-aminobutyric acid (GABA) having anticonvulsant and antinociceptive effects, used in the treatment of neuropathic pain in diabetic neuropathy and postherpetic neuralgia[.]" *Lyrica*, DORLAND'S, https://www.dorlandsonline.com (last visited Aug. 12, 2021); *Pregabalin*, DORLAND'S, https://www.dorlandsonline.com (last visited Aug. 12, 2021).

[32] The sural nerve is distributed through the "skin on back of leg, and skin and joints on later side of heel and foot[.]" *Nervus Suralis*, DORLAND'S, https://www.dorlandsonline.com (last visited July 16, 2021).

[33] Axonal neuropathy, or axonopathy, "disrupt[s] the normal function of the axons[,]" which are "the process[es] of [ ] neuron[s] by which impulses travel away from the cell body; at the terminal arborization of [ ] axon[s], the impulses are transmitted to other nerve cells or to effector organs." *Axonopathy*, DORLAND'S, https://www.dorlandsonline.com (last visited July 16, 2021); *Axon*, DORLAND'S, https://www.dorlandsonline.com (last visited July 16, 2021).

[34] Radiculopathy is "disease of the nerve roots, such as from inflammation or impingement by a tumor or a bony spur." *Radiculopathy*, DORLAND'S, https://www.dorlandsonline.com (last visited July 16, 2021).

[35] CIDP is "a slowly progressive, autoimmune type of demyelinating polyneuropathy characterized by progressive weakness and impaired sensory function in the limbs and enlargement of the peripheral nerves, usually with elevated protein in the cerebrospinal fluid." Its symptoms "often include tingling or numbness of the digits, weakness of the limbs, hyporeflexia or areflexia, fatigue, and abnormal sensations[,]" and it is most common "in young adults, particularly males[.]" *Chronic Inflammatory Demyelinating Polyneuropathy*, DORLAND'S, https://www.dorlandsonline.com (last visited July 16, 2021). Cerebrospinal fluid ("CSF") is "the fluid contained within the four ventricles of the brain, the subarachnoid space, and the central canal of the spinal cord." *Liquor Cerebrospinalis*, DORLAND'S, https://www.dorlandsonline.com (last visited July 16, 2021).

at length" and that he again "advised [Petitioner] to see Dr. Heile." *Id.* Dr. Becker stated that they would obtain an MRI scan of the "L-spine.[36]" *Id.*

On February 23, 2015, Petitioner presented to rheumatologist Trayton Mains, D.O. after receiving a referral from Dr. Tracy. Pet'r's Ex. 2 at 61. Petitioner reported "joint pain in 1st CMC,[37] elbows, wrist, hand (entire hand), knees, ankles, neck." *Id.* He stated that his symptoms in the 1st CMC and knees began "several years" prior but that he had experienced "significant progression over the past [three] months." *Id.* Petitioner reported that his pain was then most severe in his elbows, hands, and feet and ranged from a 6/10 to a 10/10. *Id.* Petitioner noted that his hand pain manifested as "generalized burning/throbbing pulsatile pain that is similar to a 'bad sunburn[.]'" *Id.* He described his knee pain as "[d]eep, dull pain that will radiate into the surrounding area." *Id.* Petitioner stated that his pain generally worsened throughout the day and was aggravated by driving, use of hands, pressure to the elbow, and weight bearing. *Id.* Petitioner noted "[g]eneralized stiffness greatest for the first few hours and greatest in the legs[,] gelling[,] and swelling of the hands and feet [that was] greatest at the end of the day." *Id.* Petitioner reported poor sleep quality and that he required elbow pads. *Id.* Petitioner also noted crepitus[38] of the knees, unsteadiness in gait, and bumping into things. *Id.* Petitioner reported that he had fallen the previous week and had experienced several near falls. *Id.* Dr. Mains noted that Petitioner had neuropathy in his feet that began approximately one year before. *Id.* Petitioner stated that he began experiencing bilateral elbow pain about eight months before and that he had been experiencing neuropathy in his arms and some below the knees over the previous five to six months. *Id.* Petitioner described the pain as a "nuclear warhead going off beneath the skin[.]" *Id.* He also noted feeling of coldness and numbness on the surface of his feet and no previous history of similar symptoms. *Id.* Additionally, a review of systems indicated fatigue, unexpected weight change, shortness of breath, and cold intolerance. *Id.* at 62. A physical exam revealed "[m]uscle strength 4+-5/5, FROM, of Synovitis[39]" in both upper and lower extremities. *Id.* at 65. Medial/lateral compression testing, anterior/posterior draw testing, and McMurray testing[40] were negative. *Id.* Dr. Mains's assessments were polyneuropathy[41] and polyarthritis.[42] *Id.* at 67.

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[36] The lumbar spine is "the part of the spine comprising the lumbar vertebrae[,]" which are "the five vertebrae [L1–L5] between the thoracic vertebrae and the sacrum. *Lumbar Spine*, DORLAND'S, https://www.dorlandsonline.com (last visited July 16, 2021); *Vertebrae Lumbales*, DORLAND'S, https://www.dorlandsonline.com (last visited July 16, 2021).

[37] The first carpometacarpal joint, or carpometacarpal joint of thumb, is "the joint formed by the first metacarpal and the trapezial bones[.]" *Articulatio Carpometacarpeae Pollicis*, DORLAND'S, https://www.dorlandsonline.com (last visited Sept. 8, 2021).

[38] Crepitus refers to "the crackling sound produced by the rubbing together of fragments of fractured bone." *Bony Crepitus*, DORLAND'S, https://www.dorlandsonline.com (last visited Oct. 21, 2021).

[39] Synovitis is "inflammation of a synovial membrane; it is usually painful, particularly on motion, and is characterized by a fluctuating swelling due to effusion within a synovial sac." *Synovitis*, DORLAND'S, https://www.dorlandsonline.com (last visited Aug. 12, 2021).

[40] McMurray testing is performed on the knee to determine whether a patient has a torn meniscus. *See McMurray Test*, DORLAND'S, https://www.dorlandsonline.com (last visited July 16, 2021).

[41] Polyneuropathy is "neuropathy of several peripheral nerves simultaneously[.]" *Polyneuropathy*, DORLAND'S, https://www.dorlandsonline.com (last visited July 16, 2021).

[42] Polyarthritis is "an inflammation of several joints together." *Polyarthritis*, DORLAND'S, https://www.dorlandsonline.com (last visited July 16, 2021).

Petitioner followed up with Dr. Becker on March 4, 2015. Pet'r's Ex. 5 at 25. Petitioner complained of a "greater than two[-]month history of memory loss and forgetfulness." *Id.* at 26. Petitioner believed that Lyrica was contributing to his memory issues. *Id.* Dr. Becker further stated that MRI of the L-spine performed on February 9, 2015, "showed L4-L5 moderate disc bulge to the right with moderate right foraminal stenosis.[43]" *Id.* Dr. Becker noted that Petitioner "still complained the pains in his hands were an [8/10 to 12/10] and in the feet a [4/10 to 8/10]." *Id.* at 25. Petitioner reported that his feet were "continu[ing] to become more numb." *Id.* at 26. Petitioner reported that he had tried using a Bio-cream without relief, and Dr. Becker advised him to increase the usage. *Id.* at 26–27. Dr. Becker and Petitioner discussed Petitioner's depression and memory issues, which Dr. Becker indicated were from pseudodementia.[44] *Id.* at 27. Dr. Becker stated that "[t]o complete [Petitioner's] work-up[,] we will obtain an EEG, antithyroglobulin Ab,[45] and Thyroperoxidase[46] level." *Id.* at 27. Petitioner was not interested in a "formal neuropsychometric[47] test." *Id.* A March 10, 2015 brain MRI "showed very mild periventricular white matter changes since prior MRI of 07-10-08 with no enhancement . . . ." *Id.* at 26. Also noting that Petitioner had a negative CSF,[48] Dr. Becker stated that his "suspicion for [multiple sclerosis ("MS")][49] is low . . . ." *Id.* at 27.

Petitioner returned to Dr. Becker on April 30, 2015. Pet'r's Ex. 5 at 21. Dr. Becker noted that an April 21, 2015 EEG was negative.[50] *Id.* at 22. Following medication adjustments, Petitioner

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[43] Stenosis is "an abnormal narrowing of a duct or canal[.]" *Stenosis*, DORLAND'S, https://www.dorlandsonline.com (last visited Aug. 12, 2021).

[44] Pseudodementia is "a disorder resembling dementia but that is not due to organic brain disease and is potentially reversible by treatment; usually due to depression or other psychiatric disorder." *Pseudodementia*, DORLAND'S, https://www.dorlandsonline.com (last visited Oct. 21, 2021).

[45] Thyroglobulin is "an iodine-containing glycoprotein of high molecular weight found in the colloid of thyroid gland follicles[.]" *Thyroglobulin*, DORLAND'S, https://www.dorlandsonline.com (last visited Sept. 24, 2021).

[46] Thyroperoxidase, or iodide peroxidase, is "an enzyme of the oxidoreductase class that catalyzes a series of reactions occurring in the synthesis of thyroxine[,]" which is "the major hormone elaborated by the thyroid follicular cells[.]" *Iodide Peroxidase*, DORLAND'S, https://www.dorlandsonline.com (last visited Sept. 24, 2021); *Thyroxine*, DORLAND'S, https://www.dorlandsonline.com (last visited Sept. 24, 2021).

[47] Neuropsychometric "pertain[s] to the quantitative testing of neurologic processes underlying cognitive processes and behaviors." *Neuropsychometric*, DORLAND'S, https://www.dorlandsonline.com (last visited Oct. 21, 2021).

[48] *See supra* note 35.

[49] Multiple sclerosis is "a disease in which there are foci of demyelination throughout the white matter of the central nervous system, sometimes extending into the gray matter[.]" *Multiple Sclerosis*, DORLAND'S, https://www.dorlandsonline.com (last visited Oct. 21, 2021).

[50] The EEG report states under "clinical history[,]" "Alzheimer's disease, the patient is very aggressive." Pet'r's Ex. 7 at 245, ECF No. 7-2. Diagnoses from the visit include Alzheimer's disease and memory loss. *Id.* at 244. In his filing in response to Respondent's Rule 4(c) report, Petitioner disputed that he had Alzheimer's or was aggressive. Petitioner wrote that he "discussed this with Dr. Becker personally . . . at [his] office visit on Monday, April 9, 2018. Dr. Becker indicated that sometimes you have to be overly broad when it comes to the verbiage of ordering and getting needed test(s) approved by insurance companies." ECF No. 42-1 at 2. Petitioner continued that the description of his clinical history may refer to a different patient, and he maintained that he "ha[s] never been aggressive during any test that [he] ha[s] taken in [his] entire life[.]" *Id.* There is no indication that Dr. Becker or any of Petitioner's providers diagnosed him with Alzheimer's.

reported that the pain in his hands decreased from a 12/10 to a 10/10, the pain in his elbows decreased from a 15/10 to an 8/10, and the pain in his feet decreased from a 12/10 to a 3/10. *Id.* at 23. Dr. Becker indicated that Petitioner "had a negative work-up for reversible causes, except his anti-thyroglobulin Ab, and Thyroperoxidase level were not done and will be reordered." *Id.* Petitioner also reported that his right foot was 80% numb and that his left foot was 40% numb. *Id.* at 22. Dr. Becker directed Petitioner to begin taking Effexor.[51] *Id.* at 23. Dr. Becker noted that he and Petitioner had previously discussed his legal claim as well as "the history of swine flu vaccination, CIDP, etc." *Id.* at 24. Dr. Becker continued that "[b]ased on [Petitioner's] description, [Petitioner] was advised I would concur that his condition was more likely than not (51%) exacerbated by his flu shot." *Id.*

On May 5, 2015, Petitioner presented to Dr. Tracy for an annual physical exam. *Id.* at 42. Petitioner reported frequent falls and worsening peripheral neuropathy. *Id.* Petitioner also noted increased anxiety, wheezing, and shortness of breath. *Id.* *Id.* at 39.

Petitioner followed up with Dr. Becker on June 8, 2015. Pet'r's Ex. 5 at 16. Dr. Becker noted that Petitioner "[t]oday . . . admits his pain was markedly increased with anxiety and the Effexor helps this. His hand pain decreased from a [10/10 to a [3/10], elbows from an [8/10] to a [5/10] and his feet are still are [sic] [3/10] . . . ." *Id.* Dr. Becker noted that Petitioner's memory problems were "still likely pseudodementia related to depression, but [on May 7, 2015,] his Thyroperoxidase level was 8.8 (0-9.0) and we discussed the possibility of Hashimoto's encephalopathy[52] at length." *Id.* at 18. Petitioner "declined a formal neuropsychometric test or a second opinion . . . at present." *Id.* Dr. Becker ordered a course of IV Solu-Medrol[53] and stated that "[i]f there is not marked improvement then [Petitioner] was advised Hashimoto's would be unlikely and it may be difficult to tell as he is also increasing his Effexor simultaneously." *Id.* at 18. Petitioner again returned to Dr. Becker on July 13, 2015. *Id.* at 11. Petitioner reported that the addition of IV Solu-Medrol had resulted in a 90% improvement in his memory. *Id.* at 12. Dr. Becker directed Petitioner to continue with this medication. *Id.* at 13.

Petitioner returned to Dr. Becker on August 4, 2015, and reported a resurgence of his speech and memory issues. Pet'r's Ex. 5 at 7. Under "past medical/surgical history[,]" Dr. Becker

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[51] Effexor, or venlafaxine hydrochloride, is "a serotonin-norepinephrine reuptake inhibitor, used as an antidepressant and antianxiety agent." *Effexor*, DORLAND'S, https://www.dorlandsonline.com (last visited Sept. 24, 2021); *Venlafaxine Hydrochloride*, DORLAND'S, https://www.dorlandsonline.com (last visited Sept. 24, 2021).

[52] Hashimoto disease is "a progressive type of autoimmune thyroiditis with lymphocytic infiltration of the gland and circulating antithyroid antibodies; patients have goiter and gradually develop hypothyroidism." *Hashimoto Disease (Thyroiditis, Struma, Encephalopathy)*, DORLAND'S, https://www.dorlandsonline.com (last visited Sept. 15, 2021); *Hashimoto Disease*, DORLAND'S, https://www.dorlandsonline.com (last visited Sept. 15, 2021). Encephalopathy is "any degenerative disease of the brain." *Encephalopathy*, DORLAND'S, https://www.dorlandsonline.com (last visited Sept. 15, 2021).

[53] Solu-Medrol is a "trademark for a preparation of methylprednisolone sodium succinate[]" and is administered via "intrasmuscular or intravenous injection." *Solu-Medrol*, DORLAND'S, https://www.dorlandsonline.com (last visited Sept. 24, 2021). Dr. Becker's notes refer to the medication as "Solomedrol."

wrote, "[p]eripheral neuropathy since 2011[.]" Pet'r's Ex. 5 at 10. Dr. Becker also included this note in Petitioner's history on September 1, 2015. *Id.* at 5.

Petitioner presented to PA-C Nancy Beach at Dr. Tracy's office on November 25, 2015, for a regular chronic pain follow-up. Pet'r's Ex. 2 at 34. The "location(s) of the pain" was described as peripheral neuropathy. *Id.* Petitioner reported "sharp, burning, throbbing[]" pain ranging from a 4/10 to a 10/10. *Id.* Petitioner noted that he was unable to complete manual labor. *Id.*

On December 2, 2015, Petitioner presented to neurologist Kevin Nelson, M.D. at the UK Kentucky Neuroscience Institute at the request of Dr. Becker. Pet'r's Ex. 13 at 41–42, ECF No. 26-1. Regarding this history of Petitioner's illness, Dr. Nelson wrote that Petitioner's "problems seem to begin in January or February 2013.[54] He notice[d] that his feet would hurt . . . and first thought they were his shoes but they turned out not to be." *Id.* at 42. Dr. Nelson continued that Petitioner "noted pain at both elbow joints [in the fall of 2014]. At around this time, his hands hurt, particularly the fingers. His motor skills and performing his jobs as a sleep technician declined." *Id.* Dr. Nelson noted that Petitioner had "no clear autonomic symptoms. He has a mild urinary urge hesitancy but otherwise no symptoms." *Id.* Dr. Nelson stated that data from Petitioner's nerve conduction study revealed "low motor amplitudes with preserved sural sensory." *Id.* Dr. Nelson also noted that Petitioner's lumbosacral MRI showed "a L4 5 herniation[55] with moderate right foraminal stenosis." *Id.* Dr. Nelson did not see data supporting that Petitioner had CTS. *Id.* Dr. Nelson continued that Petitioner's

> muscle exam shows diminished bulk in abductor hallucis[56] and EDB muscles[57] but good bulk above the ankles. He gives poor volitional effort with a coarse tremor. Giveaway weakness throughout. Deep tendon reflexes are 2+ throughout including at the ankles. He has diminished pin in a stocking distribution to the ankle. However light touch and positions are normal distally. He has no Mees lines[58] or superficial radial nerve[59] hypertrophy.

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[54] In the *pro se* submission Petitioner filed on April 16, 2018, Petitioner included a copy of a note he purportedly sent to Dr. Nelson's office requesting a correction. *See* ECF No. 42-1 at 38. Petitioner wrote that "[t]he actual date should be corrected to show 2014, not 2013." *Id.*

[55] Herniation is "the abnormal protrusion of an organ or other body structure through a defect or natural opening in a covering, membrane, muscle, or bone." *Herniation*, DORLAND'S, https://www.dorlandsonline.com (last visited July 16, 2021).

[56] The abductor hallucis is the "abductor muscle of [the] great toe[,]" which allows the great toe to abduct and flex. *Musculus Abductor Hallucis*, DORLAND'S, https://www.dorlandsonline.com (last visited July 16, 2021).

[57] The extensor digitorum brevis muscle is a "short extensor muscle of toes[,]" which allows toes to extend. *Musculus Extensor Digitorum Brevis*, DORLAND'S, https://www.dorlandsonline.com (last visited July 16, 2021).

[58] Mees lines are "single or multiple transverse white bands on the fingernails, signifying a change in composition of the nail[.]" *Mees Lines*, DORLAND'S, https://www.dorlandsonline.com (last visited July 16, 2021).

[59] The radial nerve is "distributed to [the] skin on [the] back of arm, forearm, and hand, extensor muscles on [the] back of [the] arm and forearm, and [the] elbow joint and many joints of the hand[.]" *Nervus Radialis*, DORLAND'S, https://www.dorlandsonline.com (last visited July 16, 2021).

Id. at 43.

Dr. Nelson stated that "the onset of [Petitioner's] neuropathy is unusual." *Id.* at 41. He reported that Petitioner presented with "principally distal muscle loss in the feet and subjective decreased to pin below the ankle. Otherwise there is no generalized length-dependent sensory neuropathy.[60]" *Id.* Dr. Nelson noted that Petitioner's "nerve conduction showed nerve entrapment at several sites. Carpal tunnel release was ineffective." *Id.* He continued that Petitioner did not demonstrate "clinical presentation of HNPP, nor does he have superficial radial nerve hypotrophy on examination." *Id.* Dr. Nelson stated he would be more concerned with mononeuritis multiplex[61] but that he did not "see large nerve on involvement at this point." *Id.* Dr. Nelson stated that stress was impacting Petitioner's symptoms. *Id.* He also recommended that Petitioner restart cervical traction for neck pain. *Id.*

Of the nerve tests that Dr. Nelson had performed on Petitioner that day, only the IgG against FGFR3, fibroblast growth factor receptor-3,[62] was abnormal. Pet'r's Ex. 13 at 106. In a letter to Dr. Becker, Dr. Nelson stated that "[n]ot much is known about this antibody and peripheral neuropathy." *Id.* Dr. Nelson noted that there was a single group of patients studied regarding this antibody and peripheral neuropathy but that "[t]he vast majority of" those patients "had non-length-dependent sensory findings, often with pain and ataxia[]"[63] while Petitioner's neuropathy seemed "more mixed motor/sensory and length dependent." *Id.* Dr. Nelson recommended that Dr. Becker consider an empiric course of IVIG. *Id.* Testing performed that day also revealed "[a] low-intensity IgM kappa monoclonal protein . . ." suggesting monoclonal gammopathy of undetermined significance,[64] or plasma cell dyscrasia/lymphoproliferative disorder.[65]" Pet'r's Ex. 6 at 3, ECF No. 1-7.

Following a January 11, 2016 discussion between Drs. Becker and Nelson, Dr. Becker wrote that Dr. Nelson "was puzzled by [Petitioner's] case." Pet'r's Ex. 5 at 40. The doctors

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[60] Sensory neuropathy refers to "neuropathy or polyneuropathy of sensory nerves[.]" *Sensory Neuropathy*, DORLAND'S, https://www.dorlandsonline.com (last visited July 16, 2021).

[61] Mononeuritis multiplex, or multifocal mononeuropathy, is "mononeuropathy of several different nerves simultaneously." *Multifocal Mononeuropathy*, DORLAND'S, https://www.dorlandsonline.com (last visited Sept. 8, 2021).

[62] Fibroblast growth factors are "a family of structurally related polypeptides that act as signaling molecules, binding high-affinity, ligand-dependent transmembrane receptors." *Fibroblast Growth Factor*, DORLAND'S, https://www.dorlandsonline.com (last visited July 16, 2021).

[63] Ataxia is a "failure of muscular coordination[.]" *Ataxia*, DORLAND'S, https://www.dorlandsonline.com (last visited July 16, 2021).

[64] Monoclonal gammopathy of undetermined significance, or benign monoclonal gammopathy, is "the presence of a serum M component without signs or symptoms of multiple myeloma, Waldenström macroglobulinemia, or other plasma cell neoplasms[.]" *Benign Monoclonal Gammopathy*, DORLAND'S, https://www.dorlandsonline.com (last visited July 16, 2021).

[65] Plasma cell dyscrasias are "a diverse group of neoplastic diseases involving proliferation of a single clone of cells producing a serum M component (a monoclonal immunoglobulin or immunoglobulin fragment)[.]" *Plasma Cell Dyscrasias*, DORLAND'S, https://www.dorlandsonline.com (last visited Aug. 12, 2021). Lymphoproliferative disorders "encompass[] a variety of disorders characterized by abnormal proliferation of lymphocytes[.]" *Lymphoproliferative Disorders*, DORLAND'S, https://www.dorlandsonline.com (last visited Aug. 12, 2021).

discussed potential IV treatment. *Id.* Dr. Becker also wrote, "[w]e discussed medical legal issues at length[,] and Dr. Nelson did not feel [Petitioner's] neuropathy was related to his flu shot." *Id.*

Petitioner followed up with Dr. Nelson on February 25, 2016, and reported worsening symptoms over the past few weeks. Pet'r's Ex. 6 at 1, ECF No. 1-7. Petitioner complained that his feet felt like they were burning whereas they were previously numb. *Id.* Petitioner also reported "pulsatile discomfort in his entire hands as well as pain in his elbows[,]" which Dr. Nelson wrote "does not seem to be joint related nor . . . typical neuropathic kind of pain." *Id.* Regarding the FGFR3 antibody previously found, Dr. Nelson wrote that "[t]he neurologic manifestations associated with this are unusual and diverse. Possibly this antibody titer is related to his symptoms. He has few classic neuromuscular finding by physiologically or on neuromuscular examination." *Id.* Dr. Nelson indicated that he had written for Petitioner "to be evaluated by the hemoptic [sic] group here for his IgM monoclonal gammopathy of unknown significance[]" and that he had asked a rheumatologist for an opinion whether Petitioner had a systemic autoimmune disorder. *Id.* Dr. Nelson stated that "[a]ntifibroblast growth factor receptor 3 antibodies are [oftentimes] associated with systemic autoimmune disorders." *Id.* Dr. Nelson prescribed a course of Medrol[66] and stated that he did not want Petitioner to try further immunosuppression until he had more information regarding whether Petitioner had a systemic illness. *Id.*

On March 17, 2016, Petitioner presented to Lawrence Zeff, M.D., at Dr. Tracy's office. Pet'r's' Ex. 2 at 17. Petitioner complained of low back and bilateral leg pain that he had been experiencing for ten years. *Id.* Petitioner reported pain that was "stabbing, sharp, and radiating down the bilateral leg." *Id.* The note continued that Petitioner had "severe numbness and tingling in both legs . . . and difficulty with ambulation." *Id.* Dr. Zeff stated that Petitioner's "symptoms were likely due to peripheral neuropathy." *Id.* at 20.

Petitioner returned to Dr. Zeff on March 31, 2016, for "re-evaluation of neck pain." Pet'r's Ex. 2 at 12. Petitioner noted continuing numbness and tingling in his arms and legs. *Id.* Dr. Zeff reviewed the results of Petitioner's cervical spine[67] MRI. *See id.* Dr. Zeff's impressions were "[d]egenerative disc disease cervical spine with a protruding disc at C6-C7[, p]ain syndrome[, and p]eripheral neuropathy." *Id.* at 12–13.

On May 26, 2016, Petitioner followed up with Dr. Zeff regarding his neck pain. Pet'r's Ex. 2 at 10. The note indicates that Petitioner reported "exacerbation of neck pain[]" that "isn't [sic] present for the past [six] weeks." *Id.* Petitioner complained of pain when flexing, extending his cervical spine, and when rotating his cervical spine. *Id.* Petitioner denied that this pain was referred to his arms. *Id.* A physical exam revealed "decreased range of motion in the cervical spine[]" but good upper extremity muscle strength. *Id.* Petitioner also demonstrated decreased upper extremity

[66] Medrol is a trademark for methylprednisolone. *Medrol*, DORLAND'S, https://www.dorlandsonline.com (last visited Aug. 12, 2021).

[67] The cervical spine is "the part of the spine comprising the cervical vertebrae[,]" which are in the neck. *Cervical Spine*, DORLAND'S, https://www.dorlandsonline.com (last visited Oct. 21, 2021); *Cervical Vertebrae*, DORLAND'S, https://www.dorlandsonline.com (last visited Oct. 21, 2021).

reflexes and normal gait. *Id.* Dr. Zeff's impressions were "[c]ervical spondylosis with bilateral C4-C5 and C5-C6 facet joint arthropathy[68] [and c]hronic pain syndrome." *Id.*

Petitioner presented to Dr. Tracy on June 29, 2016, for re-evaluation of chronic anxiety as well as a regular chronic pain follow-up. *Id.* at 7. The location of Petitioner's pain was listed as "neuropathy in hands and feet." *Id.* Petitioner reported "burning, throbbing" pain ranging from a 6/10 to a 16/10 and continued to report that he was "[u]nable to complete manual labor." *Id.* Petitioner noted bilateral elbow pain as well as hand and feet pain. *Id.* at 8. The working diagnosis also included OA of bilateral elbow. *Id.*

On January 4, 2017, Petitioner returned to Dr. Nelson. Pet'r's Ex. 13 at 12. Dr. Nelson noted that Petitioner complained of "exploding" pain in his feet, elbows, hands, and shoulders. *Id.* Dr. Nelson described Petitioner positive antifibroblast growth factor receptor 3 as an "antibody syndrome that is poorly characterized, likely it's unrelated to his problems . . . ." *Id.* Dr. Nelson noted that Petitioner had fallen eight times in recent months and experienced urinary hesitancy. *Id.* The physical exam revealed "hyperreflexia[69] with clonus[70] at both knees and ankles." *Id.* Petitioner's arm reflexes were "3+ with Hoffmann signs.[71]" *Id.* Dr. Nelson continued that "[Petitioner] has a negative jaw jerk. Position sense is relatively normal in both great toes. N[o] spinal level to pin. He has giveaway weakness of the biceps." *Id.* Dr. Nelson described Petitioner's gait as "slow[] and flexed." *Id.* Dr. Nelson noted that "[t]he hyperreflexia is a new and troubling sign. [Petitioner] has had neck pain in the past[,] but when I saw him in December 2015[,] my records indicate normal reflexes (2+)." *Id.* Dr. Nelson stated that he was "concerned that [Petitioner] is developing a myelopathy[72] either the cervical or less likely thoracic[73] level." *Id.*

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[68] Facet joint arthropathy, or facet osteoarthritis, is "a type of spondylarthritis centered in facet joints, with disk degeneration and pain[.]" *Facet Osteoarthritis*, DORLAND'S, https://www.dorlandsonline.com (last visited Aug. 12, 2021).

[69] Hyperreflexia is dysreflexia, "or disordered response to stimuli[,]" that is "characterized by exaggeration of reflexes." *Hyperreflexia*, DORLAND'S, https://www.dorlandsonline.com (last visited Oct. 21, 2021); *Dysreflexia*, DORLAND'S, https://www.dorlandsonline.com (last visited Oct. 21, 2021).

[70] Clonus is "alternate muscular contraction and relaxation in rapid succession[]" or "a continuous rhythmic reflex tremor initiated by the spinal cord below an area of spinal cord injury, set in motion by reflex testing." *Clonus*, DORLAND'S, https://www.dorlandsonline.com (last visited Oct. 21, 2021).

[71] Hoffmann phenomenon, or Hoffmann sign, refers to "increased excitability to electrical stimulation in the sensory nerves[.]" *Hoffmann Phenomenon*, DORLAND'S, https://www.dorlandsonline.com (last visited Oct. 21, 2021). Hoffman sign also means "in hemiplegia, a sudden nipping of the nail of the index, middle, or ring finger will produce flexion of the terminal phalanx of the thumb and of the second and third phalanges of some other finger." *Hoffman Sign*, DORLAND'S, https://www.dorlandsonline.com (last visited Oct. 21, 2021).

[72] Myelopathy refers to "any of various functional disturbances or pathologic changes in the spinal cord, often referring to nonspecific lesions in contrast to the inflammatory lesions of myelitis." *Myelopathy*, DORLAND'S, https://www.dorlandsonline.com (last visited July 16, 2021). Myelitis is "inflammation of the spinal cord, often part of a more specifically defined disease process." *Myelitis*, DORLAND'S, https://www.dorlandsonline.com (last visited July 16, 2021).

[73] Thoracic pertains to the chest. *Thoracic*, DORLAND'S, https://www.dorlandsonline.com (last visited Oct. 21, 2021).

Petitioner presented for MRIs of the cervical and thoracic spine[74] on February 16, 2017. *Id.* at 52, 54. The impression regarding the cervical spine was "[m]ultilevel degenerative changes, including neural foraminal stenosis at multiple levels, ranging from mild to severe. Spinal stenosis is most pronounced at C3-4, where it is mild to moderate." *Id.* at 53. The impression following the thoracic spine MRI was "[m]ultilevel disc osteophyte[75] complexes and degenerative changes without significant spinal or neural foraminal stenosis." *Id.* at 55.

On September 15, 2017, a treatment plan was developed for Petitioner that involved skilled nursing, occupational therapy, and physical therapy. Pet'r's Ex. 14 at 3, ECF No. 29-1. The diagnoses associated with this plan included "other intervertebral disc degeneration, lumbosacral region[,]" "polyneuropathy, unspecified[,]" "difficulty walking, not elsewhere classified[,]" "chronic pain syndrome[,]" and "essential (primary) hypertension[.]" *Id.* Petitioner had twelve home physical therapy visits and seven home occupational therapy visits through November 2017. *See generally* Pet'r's Ex. 14. Petitioner "expresse[d] frustration with continued pain, and doctors not knowing what is causing it, frustrations with pain in hands mostly and unable to use the pain [sic]." *Id.* at 7. Petitioner reported pain ranging from an 8/10 to a 10/10 in his hands and wrists as well as pain rated as a 1/10 in his ankles. *Id.* at 8. Petitioner did not file subsequent relevant medical records.

B. Petitioner's Affidavit

Petitioner filed an affidavit along with his petition on October 28, 2016. Pet'r's Ex. 1, ECF No. 1-2. Petitioner asserted that prior to his vaccination, he "was one of the top [five] sleep technicians in the world . . . [and] was fully capable of driving, working, exercising, moving around, speaking without difficulty, and had a great memory." *Id.* ¶ 3. Petitioner stated that "[w]ithin days after" his vaccination, he "developed extreme fatigue and weakness." *Id.* ¶ 4. He reported that "[o]n November 2, 2013, [he] laid down to sleep due to exhaustion and fatigue and did not again realize consciousness for approximately five (5) days, or until November 6, 2013." *Id.* Petitioner stated that he "thought that [he] was dying[]" and described his condition as a "comatose state[.]" *Id.* In response to Respondent's Rule 4(c) report, Petitioner later clarified that this was "a comatose[-]like state[.]" ECF No. 42-1 at 2, 35. Petitioner continued that he "felt so ill during that time frame, that [he] had no recollection of what happened." *Id.* at 2. He clarified that while he "fe[lt] like [he] was going to die," he "ha[s] no idea at what point in time that [he] felt like that; maybe some point between Saturday and Tuesday: maybe when he called the Dr. on Wednesday[] . . . ." *Id.*

Petitioner acknowledged that he had "some health issues" prior to his vaccination but maintained that he "had never experienced the symptoms as those [he] experienced after this flu shot." Pet'r's Ex. 1 ¶ 5. Petitioner stated that following his vaccination, he "continued to decline in health and developed worsening peripheral neuropathy, numbness of [his] extremities, memory issues, shortness of breath, fatigue, and severe, shooting pain throughout [his] body." *Id.* ¶ 7.

[74] The thoracic spine is "the part of the spine comprising the thoracic vertebrae." *Thoracic Spine*, DORLAND'S, https://www.dorlandsonline.com (last visited Oct. 21, 2021).
[75] An osteophyte is "a bony excrescence or osseous outgrowth." *Osteophyte*, DORLAND'S, https://www.dorlandsonline.com (last visited Oct. 21, 2021).

Petitioner further noted "burning and freezing sensations in [his] limbs," constant pain in his hands and elbows, trouble speaking, changes to his gait, and fatigue. *Id.*

C. Opinions and Medical Literature

1. Letters from Petitioner's Treating Providers

Dr. Becker wrote two letters opining on the relationship between Petitioner's peripheral neuropathy and vaccination. Pet'r's Exs. 17, 19, ECF Nos. 66-3, 71-1. Speaking on his education and experience, Dr. Becker stated that he "graduated from Northwestern University Feinberg School of Medicine in 1982[and] completed a two[-]year neuro pathology fellowship at Johns Hopkins [University]." Pet'r's Ex. 19 at 1. After spending a year on the Johns Hopkins faculty, Dr. Becker began practicing neurology in Kentucky. *Id.* As of February 2019, Dr. Becker stated that he had been practicing neurology for nearly thirty years. *Id.*

Dr. Becker wrote his first letter on April 12, 2018. Pet'r's Ex. 17. Dr. Becker stated that Petitioner's EMG/NCV revealed peripheral neuropathy and that "[e]xtensive workup for reversible causes was otherwise unrevealing." *Id.* Dr. Becker stated that he "feel[s] that it is more likely than not that [Petitioner's] neuropathy was related to his flu shots." *Id.* Dr. Becker noted that he had thus advised Petitioner to abstain from future flu shots. *Id.*

Dr. Becker wrote his second letter on February 13, 2019. Pet'r's Ex. 19. Dr. Becker stated that "[a]lthough [Petitioner] experienced some minor pain in his arms and hands (greater than feet) from 2011 to 2013, his problems significantly worsened after receipt of an influenza vaccination in 2013." *Id.* at 1. Dr. Becker continued:

> We will never know for sure what happened to [Petitioner]. I do not believe he is faking his condition nor does a conversion disorder fully explain his condition, and/or the supportive diagnostic evidence. Based on the medical history and the timing of the significant worsening of his complaints[,] I believe the influenza vaccination that [Petitioner] received in 2013 more likely than not significantly aggravated his condition. Furthermore, I believe the influenza vaccination more likely than not contributed to his continuing neurological suffering.

Id. at 1–2.

Dr. Tracy wrote a letter regarding Petitioner's condition on February 7, 2019. Pet'r's Ex. 18, ECF No. 70-1. Dr. Tracy stated that he earned his medical degree from Wright State University and is certified by the American Board of Family Medicine. *Id.* Dr. Tracy wrote that he had been Petitioner's PCP for more than twenty years and is familiar with both Petitioner's pre- and post-vaccination health. *Id.* Dr. Tracy noted, "[p]rior to this [October 2013] vaccination, [Petitioner] did have symptoms of chronic pain, mostly in his hands and back. While these complaints were chronic, they were not incapacitating, and [Petitioner] was able to continue to do activities of daily living and work full time." Dr. Tracy noted that when Petitioner presented to him with "extreme weakness and fatigue[]" seven days post vaccination, "[t]hese complaints were worse than what [Dr. Tracy] had seen in [Petitioner] previously, and [Petitioner] felt like something was definitely

wrong." *Id.* Dr. Tracy continued that Petitioner was concerned at that time that he was having an adverse response to his recent vaccination. *Id.*

Dr. Tracy reported that he did not see Petitioner again until March 2014, when he diagnosed Petitioner with peripheral neuropathy. *Id.* Dr. Tracy noted, "[t]his was not a diagnosis that [Petitioner] had prior to vaccination." *Id.* Speaking on the relationship between Petitioner's peripheral neuropathy and vaccination, Dr. Tracy wrote:

> We will never know for sure what caused [Petitioner's] peripheral neuropathy, if it was a new neurological process, or if it was a worsening from a pre-existing condition. However, there is a logical sequence of cause and effect between his influenza vaccination he received on October 30, 2013 and his significant worsening immediately thereafter. The timing would certainly fit with the premise that the vaccination was a significant contributing factor to [Petitioner's] progressive worsening of his condition.

Id.

2. Petitioner's Report from Aaron Haubner, Ph.D.

Petitioner filed a "review and report" authored by his brother, Aaron J. Haubner, Ph.D., on February 6, 2019. Pet'r's Ex. 15, ECF No. 66-1. Dr. Haubner's curriculum vitae ("CV") indicates that he obtained a Bachelor of Science degree in biology from the University of Kentucky in 1998 and completed his Ph.D. in Pharmacology[76] at the University of Kentucky College of Pharmacy in 2007 or 2008. *See* Pet'r's Ex. 16 at 1, ECF No. 66-2. Following receipt of his bachelor's degree, Dr. Haubner worked as a staff scientist between 1998 and 2000 and a teaching assistant between 2000 and 2002 at the University of Kentucky College of Pharmacy. *Id.* Dr. Haubner was a visiting research scientist at University College London in 2005 and a postdoctoral researcher at Southern Research Institute in 2007. *Id.* He was a member of the American Association of Pharmaceutical Sciences from 2002 to 2007, the Kentucky chapter of the Society of Neuroscience from 2003 to 2006, and the Kentucky Academy of Science from 1998 to 2000. *Id.* at 2. Dr. Haubner listed six publications, which were published in 2002, 2003, 2004, and 2013. *See id.* at 2–3. Dr. Haubner is also an author of conference presentations and posters from between 1998 and 2006. *See id.* at 3–4. There is no indication that Mr. Haubner's publications or research related to vaccines. Dr. Haubner also completed an MBA at New Charter University between 2012 and 2017. *Id.* at 1.

Dr. Haubner begins his report with what he describes as a "plausible medical theory of causation." Pet'r's Ex. 15 at 1. Dr. Haubner explains that clinical and scientific literature "supports the concept that vaccines can induce a chronic autoimmune condition based on the biochemical principle of molecular mimicry. This is when antibodies produced to identify and induce attack on the vaccine-targeted pathogen unintentionally binds to non-specific 'off-target' sites." *Id.*

[76] Pharmacology is "the science that deals with the origin, nature, chemistry, effects, and uses of drugs; it includes pharmacognosy, pharmacokinetics, pharmacodynamics, pharmatherapeutics, and toxicology." *Pharmacology*, DORLAND'S, https://www.dorlandsonline.com (last visited Sept. 13, 2021).

Dr. Haubner cites various papers, including Yahel Segal and Yehuda Shoenfeld's *Vaccine induced autoimmunity: the role of molecular mimicry and immune cross reaction*. Pet'r's Ex. 28, ECF No. 83-8.[77] Drs. Segal and Shoenfeld stated that "[m]olecular mimicry refers to a significant similarity between certain pathogenic elements contained in the vaccine, and specific human proteins. This similarity may lead to immune cross-reactivity wherein the reaction of the immune system towards the pathogenic antigens may harm the similar human proteins, essentially causing autoimmune disease." *Id.* The authors used the concept of molecular mimicry to examine the relationships between certain vaccines and conditions. *See id.* at 6–17. In particular, the authors discussed research linking narcolepsy and Guillain-Barré Syndrome ("GBS")[78] to H1N1 flu vaccines, including adjuvanted vaccines. *Id.* at 6. The authors stated that GBS is "believed to result from an autoimmune assault to the peripheral nervous system." *Id.* at 8. They asserted that "[s]tudies have demonstrated molecular similarity between a component of [a bacterium associated with approximately thirty percent of GBS cases] and GM1, one of the targets of the autoantibodies found in patients, suggesting a role of molecular mimicry in the pathogenesis of the disease." *Id.* at 8–9. Segal and Shoenfeld continued that because there are multiple "infectious potential triggers" of GBS, including the influenza virus, it is "of no surprise that various associations have been reported between [flu] vaccines and GBS." *Id.* at 9. The authors stated that "[d]ata obtained of more than [seventy] million vaccinated subjects, from over ten countries, was analyzed and revealed a 2-3 fold increased risk of GBS in the [forty-two] days following recipient [sic] of the 2009 influenza vaccines." *Id.* (internal citations omitted).

Dr. Haubner also cites "[a] review by Chavada and Willison[, which he claims] catalogs numerous instances over the prior [twenty-five] years where autoantibodies directed against native tissue, and peripheral nerve glycans[79] specifically, have caused neuropathies." Pet'r's Ex. 15 at 2.; *see* Pet'r's Ex. 24, ECF No. 83-4.[80] He claims that "[t]his research confirms that '[b]asic studies continue to support a direct role for autoantibodies in neuropathy pathogenesis.'" Pet'r's Ex. 15 at 2 (quoting Pet'r's Ex. 24 at 1). Chavada and Willison's paper "review[ed] the recent literature related to various antibody targets associated with peripheral neuropathies, highlighting recent advances in the field." Pet'r's Ex. 24 at 1. In surveying recent literature, Chavada and Willison discussed various neuropathies, including GBS and AIDP,[81] antibodies that have been found in

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[77] Yahel Segal and Yehuda Shoenfeld, *Vaccine induced autoimmunity: the role of molecular mimicry and immune cross reaction*, CELL MOL IMMUNOL 2018 Mar. 5. Epub Ahead of Print.

[78] GBS is "rapidly progressing ascending motor neuron paralysis of unknown etiology, frequently seen after an enteric or respiratory infection. An autoimmune mechanism following viral infection has been postulated. It begins with paresthesias of the feet, followed by flaccid paralysis of the entire lower limbs, ascending to the trunk, upper limbs, and face[.]" It can also include "slight fever, bulbar palsy, absent or lessened tendon reflexes, and increase protein in the [CSF] without a corresponding increase in cells." *Guillain-Barré Syndrome*, DORLAND'S, https://www.dorlandsonline.com (last visited July 16, 2021).

[79] Glycans, or polysaccharides, are "carbohydrate[s] that on hydrolysis yield[] a large number of monosaccharides [ ]. *Glycan*, DORLAND'S, https://www.dorlandsonline.com (last visited Oct. 21, 2021); *Polysaccharide*, DORLAND'S, https://www.dorlandsonline.com (last visited Oct. 21, 2021).

[80] Govind Chavada and Hugh J. Willison, *Autoantibodies in immune-mediated neuropathies*, 25 CURR OPIN NEUROL. 550 (2012).

[81] AIDP, or acute inflammatory demyelinating polyradiculoneuropathy, is a is type of GBS. *See Acute Inflammatory Demyelinating Polyradiculoneuropathy*, DORLAND'S, https://www.dorlandsonline.com (last visited Sept. 8, 2021).

patients with various types of neuropathies, including "autoantibodies to distinct gangliosides[82] and glycolipids[,][83]" and work that has been done exploring the role of various antibodies in the pathogenesis of various neuropathies. The authors specifically noted that "evidence continues to emerge supporting the hypothesis that the pathophysiology of GBS is an antibody-mediated disorder driven in part by molecular mimicry with microbial products." *Id.* at 1–2. Although the authors briefly discussed the flu vaccine, they noted specifically that "[s]ince the first report of a suspected link between GBS and [flu] vaccine in 1976, most subsequent studies performed to evaluate the risk of developing GBS after [flu] vaccination have been negative." *Id.* at 4. They further noted that a recent study of "prevaccination and postvaccination sera for anti-influenza antibodies and [antiganglioside antibodies ("AGAbs")], in 1000 humans and in mice . . . did not find any association between GBS, AGAbs and [flu] vaccine." *Id.*

Dr. Haubner also cites a paper by Schattner, which he claims supports that patients have experienced autoimmune disease post viral vaccinations. Pet'r's Ex. 15 at 2; *see* Pet'r's Ex. 27, ECF No. 83-7.[84] Schattner's review explored links between various vaccines and various autoimmune, or likely autoimmune, conditions.

Dr. Haubner continues, citing a case report by Tay and Chan, that "[flu] vaccine-mediated muscle weakness has not only been reported in patients with a prior history of existing related symptoms." Pet'r's Ex. 15 at 3; *see* Pet'r's Ex. 29, ECF No. 83-9.[85] Although the patient described in Tay and Chan's report had a CIDP diagnosis, Dr. Haubner states that "[t]he patient in this case has most of the same symptoms as the [p]etitioner in the instant case and provides further real-world evidence to support the autoimmunity-based theory of injury." Pet'r's Ex. 15 at 3.

Dr. Haubner further claims that "[t]his line of scientific investigation into the leading mechanism of pathology is further supported by large and robust epidemiological studies on the subject." *Id.* He discusses a paper by Vaughn et al., which related H1N1 and N5N1 flu vaccines to immune-related conditions. *Id.*; *see* Pet'r's Ex. 30, ECF No. 83-10.[86] Dr. Haubner also discusses a case report by Barros and de Carvalho, which involved a patient who purportedly experienced autoimmune/inflammatory syndrome induced by adjuvants ("ASIA") and suffered various symptoms. *Id.*; *see* Pet'r's Ex. 23, ECF No. 83-3.[87] Dr. Haubner asserts that the symptoms the

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[82] Gangliosides are "any of a group of glycosphingolipids in which the polar head group on ceramide is a sialic acid-containing oligosaccharide linked via a glucose residue; they occur predominantly in tissues of the central nervous system." *Ganglioside*, DORLAND'S, https://www.dorlandsonline.com (last visited Oct. 21, 2021).

[83] Glycolipids are "lipid[s] containing carbohydrate groups . . . the term is used almost exclusively to denote the sphingosine derivatives lacking phosphate groups (glycosphingolipids)." *Glycolipids*, DORLAND'S, https://www.dorlandsonline.com (last visited Oct. 21, 2021).

[84] Ami Schattner, *Consequence or coincidence? The occurrence, pathogenesis and significance of autoimmune manifestations after viral vaccines*, 23 VACCINE 3876 (2005).

[85] Shee Yen Tay and Wing P. Chan, *A 9-Year-Old Female with Bilateral Leg Weakness After Influenza Vaccination*, 43 PEDIATRIC ANNALS 440 (2014).

[86] David W. Vaughn et al., *Safety of AS03-adjuvanted inactivated split virion A(H1N1)pdm09 and H5N1 influenza virus vaccines administered to adults: Pooled analysis of 28 clinical trials*, 10 HUM. VACCINES & IMMUNOTHERAPEUTICS 2942 (2014).

[87] Solange M. Barros & Jozélio Freire de Carvalho, *Shoenfeld's Syndrome After Pandemic Influenza A/H1N1 Vaccination*, 36 ACTA REUMATOL PORT. 65 (2011).

patient in that report suffered are "nearly identical to those that the [p]etitioner either developed recently following the flu vaccination or [that] became empirically worse according to the medical records and expert medical diagnoses [ ]." Pet'r's Ex. 15 at 3. Dr. Haubner continues that "[w]hile most reports by the clinicians and research scientists tend to dance around the topic for obvious political reasons related to job security, [Barros and de Carvalho] are brave enough to state plainly, 'this clinical case helps to establish the diagnosis of [ASIA] . . . ." *Id.* at 3–4 (quoting Pet'r's Ex. 23 at 2). Dr. Haubner continues, discussing another paper[88] on ASIA, which related ASIA to flu vaccines.

Furthermore, Dr. Haubner asserts that "it is well established and accepted by the [Program] that the flu vaccine is known to cause [GBS]." *Id.* at 4. Listing symptoms associated with GBS, he avers that case reports and analysis "provide strong real-world evidence that the [flu] vaccine can lead to GBS symptoms." *Id.*

Dr. Haubner argues that "the literature supporting the unintended causal link between vaccines, and the influenza vaccine in particular, and molecular mimicry as the basis of vaccine-induced autoimmune injury is deep and well-established." *Id.* at 5. He continues that "there remains little doubt that a vaccine-induced antibody's non-specific cross reactivity with native tissues is the major mechanistic basis and is a cause of vaccine-related autoimmune diseases like that suffered by the [p]etitioner." *Id.* He states that the medical literature he presents "expressly state[s] that there exists a causal relationship between vaccines in general, and the influenza vaccine specifically and its adjuvants, and autoimmune-related chronic neuropathy." *Id.*

Dr. Haubner discusses Petitioner's pre-vaccination conditions. Pet'r's Ex. 15 at 5–6. Dr. Haubner opines that Petitioner's pre-vaccination conditions, including CTS, thyroid irregularity, cervical stenosis, etc., are unrelated to Petitioner's post-vaccination condition because they were previously diagnosed and, unlike Petitioner's post-vaccination condition, did not cause "disability and/or dysfunction sufficient to cause major handicap . . . ." *Id.* at 6. Thus, Dr. Haubner recommends that Petitioner's preexisting conditions be "set aside[]" in the evaluation of [his] claim. *Id.*

Regarding Petitioner's post-vaccination condition, Dr. Haubner states that Petitioner experienced "a severe, acute-phase response, suggesting an immune or neuroinflammatory reaction" that subsided, allowing Petitioner to function in work and daily functioning. *Id.* at 7. Dr. Haubner states that Petitioner's March 2014 diagnosis of peripheral neuropathy "due to rapidly progressing and worsening pain and motor dysfunction, particularly in the lower extremities (new) . . . was just [five] months post-acute phase reaction, providing for a reasonable timeframe from Petitioner's development of new [peripheral neuropathy] symptoms and dysfunctions." *Id.* Dr. Haubner characterizes Petitioner's reaction as "two distinct phases/injuries . . . a severe acute-phase response and . . . chronic neuromuscular-inflammatory degenerative phase . . . that was experienced beginning in the months following the acute phase" and worsening in the following years. *Id.* at 8. Dr. Haubner continues that because Petitioner's post-vaccination condition included new symptoms and a new diagnosis, "it is more likely that [Petitioner's] reaction to the vaccine led to a novel debilitating condition." *Id.* at 9. Furthermore, Dr. Haubner refers to Petitioner's

[88] Luis J. Jara et al., *Severe manifestations of autoimmune syndrome induced by adjuvants (Shoenfeld's syndrome)*, 65 IMMUNOL RES 8 (2017).

complaints of pain and discomfort from before his vaccination, including his May 2016 claim that he had been in pain for ten years, as "potentially confusing facts and unintentional 'red herrings[.]'" *Id.* at 9–10. In sum, Dr. Haubner denies that any of Petitioner's pre-vaccination symptoms are related to his peripheral neuropathy.

Regarding a "logical sequence of causality," Dr. Haubner asserts that the evidence and medical literature "linking vaccines in general, and the [flu] vaccine specifically, with debilitating symptoms of chronic peripheral- and polyneuropathy, provides [a] logical sequence of causality . . . ." *Id.* at 11. He states that "[n]umerous medical and scientific authors have made the direct connection, linking the [flu] vaccine with serious neuropathic debilitation . . . ." *Id.* Dr. Haubner continues that "Petitioner experienced a severe acute-phase response followed by increasingly severe motor and sensory symptoms. This has never been questioned[.]" *Id.* He claims that Petitioner's peripheral neuropathy diagnosis in "2014/2015 . . . fits with a logical temporal and causal relationship." *Id.* at 12. Dr. Haubner further notes that Dr. Tracy provided documentation to allow Petitioner to receive a medical exemption for the 2014 flu vaccine due to his adverse reaction to the previous vaccine. *Id.* Dr. Haubner concludes that "[u]ntil a reasonable alternative explanation for the origin of the severe reaction and novel chronic debilitation is put forward, in [Dr. Haubner's] opinion, one should assume that the vaccine injury is the most likely cause of Petitioner's substantial deterioration in health." *Id.* at 13.

3. Respondent's Expert Report – Ross Kedl, Ph.D.

Ross M. Kedl, Ph.D. has been a professor of immunology at the University of Colorado Denver School of Medicine since 2004. Resp't's Exs. A–B, ECF Nos. 79-1–79-2. He earned a Ph.D. in Pathobiology from the University of Minnesota in 1997. Resp't's Ex. A at 1. He "ha[s] maintained an NIH funded research program centered on the biology of vaccine adjuvants and their capacity to induce robust and enduring cellular immunity[]" as well as "NIH funded projects on the study of antigen inexperienced T cell memory subsets [and] funding devoted to the role of lymphatic endothelial cells in the management of T cell memory after vaccination or viral challenge." *Id.* Before entering academia, he authored or co-authored eleven patents related to "elicitation of immunity via vaccine adjuvants." *Id.* Over his career, he has "more than [twenty] years experience . . . in evaluating the influence of vaccine adjuvants . . . on the induction of local and systemic inflammation and its eventual induction of downstream adaptive immunity." *Id.* at 2.

Dr. Kedl is highly critical of Dr. Haubner's report. Dr. Kedl states that Dr. Haubner's "expressed opinions are not those of one familiar with the literature of state of the art in either immunology or vaccinology, basic or applied." *Id.* at 3. In addition to questioning Dr. Haubner's qualifications and argument structure, Dr. Kedl argues that:

> Dr. Haubner 1) extends himself beyond the boundaries of the established literature on the validity of molecular mimicry as a bona fide mechanism of neurological injury, 2) provides no evidence that any of these hypothetical mechanisms apply to [Petitioner] and his idiopathic injury, 3) does not fully appreciate the epidemiological data contradicting any significant role for vaccination in the cause of neuropathology, and 4) insufficiently considers the far more probable

> relationship between [Petitioner's][89] extensive list of pre-existing conditions in the development of idiopathic neuropathy.

Id.

Dr. Kedl asserts that Petitioner has idiopathic neuropathy rather than an inflammatory neuropathy such as GBS, AIDP, or CIDP. *Id.* at 4. He states that "it is critical to emphasize that nothing in [Petitioner's] medical record, nor his varying diagnoses, indicates that he is suffering from an immune mediated, demyelinating neuropathy." *Id.* He asserts that Petitioner's "exaggerated malaise" lasting for some days post vaccination is "easily explain[ed]" by Petitioner's subsequent diagnosis of hypothyroidism. *Id.* Dr. Kedl further notes that, during the four to five months following Petitioner's vaccination, "[he] experienced none of the symptoms associated with an acute inflammatory neurological event such as seen in GBS/AIDP, and thus these can be ruled out. Similarly, there is no medical evidence of demyelination as the cause for his continued deterioration into overt neuropathy." *Id.* Dr. Kedl continues, explaining that "[t]his is critical to acknowledge as fact because Dr. Haubner consistently obfuscates the issues by conceptually conflating 'neuropathy' with GBS/AIDP and/or CIDP." *Id.* Dr. Kedl notes that the literature cited by Dr. Haubner is geared toward the latter conditions. *Id.*

Dr. Kedl is further critical of Dr. Haubner's characterizations of medical literature. *See id.* Specifically addressing Dr. Haubner's characterization of the Chavada and Willison article, Dr. Kedl rejects Dr. Haubner's assertion that the authors claimed instances in which autoantibodies caused neuropathies. *Id.* Dr. Kedl notes that the Chavada and Willison paper described studies that, regarding ganglioside antibodies and the flu vaccine, "did not find any association between GBS, AGAbs and influenza vaccine." *Id.* (quoting Pet'r's Ex. 24 at 44). Dr. Kedl also notes that the authors of the Chavada and Willison paper "emphasized the potential usefulness of glycan-reactive antibodies as potential biomarkers of disease, and only speculating as to their possible, but as of yet unproven role in pathology. In fact, they even go as far as to state that no reliable immune targets have been found for AIDP and CIDP[.]" *Id.* Dr. Kedl further asserts that "as those well versed in immunology are familiar with, simple detection of antibodies reacting with self-antigens can be found in all healthy individuals. Thus, simply identifying autoantibodies does not equate with any pathology." *Id.*

Dr. Kedl next asserts that "[t]he seasonal flu vaccine does not induce autoantibodies via the unproven mechanism of molecular mimicry." *Id.* He rejects Dr. Haubner's characterization of "molecular mimicry as the '[] prevailing theory of all autoimmune related conditions[,]'" as well as his claim of a causal link between peripheral nerve glycans and neuropathies. *Id.* at 5; *see* Pet'r's Ex. 15 at 2 Dr. Kedl states that "a large body of literature [ ] stands in sharp contrast to the assertion that there is any causal relationship between ganglioside(glycan)-specific antibodies and even GBS." Resp't's Ex. A at 5. Specifically, Dr. Kedl notes that Chavada and Willison did not identify a "clear [or] consistent" association between AIDP and "antiglycolipid or other autoantibodies." *Id.* (quoting Pet'r's Ex. 24 at 2). Dr. Kedl cites an additional review, which states that "the majority of GBS patients [of the AIDP subtype] have no identified autoantibodies, so the pathogenesis of

[89] Dr. Kedl refers to Petitioner by an incorrect name.

the disease is still debated[.]" *Id.* (quoting Resp't's Ex. A, Tab 5, ECF No. 80-5[90] at 2). Dr. Kedl further claims that "reports of experimentally induced ganglioside specific antibody mediated pathology as a result of immunization are misleading and contradictory[]" because "[t]hese studies are always performed with repeated immunizations of large amounts [ ] of gangliosides emulsified in heat killed mycobacteria and mineral oil, otherwise known as Complete Freunds Adjuvant (CFA)." *Id.* He continues that CFA is "clinically unstable due to the toxic levels of chronic inflammation it induces." *Id.* Dr. Kedl notes that, nevertheless, "one study documented, '[n]o neurological or behavioral abnormality . . . during the period of antiserum production[and n]o obvious pathological changes, including demyelination[.]" *Id.* (quoting Resp't's Ex. A, Tab 9, ECF No. 80-9[91] at 1). The authors of that study believed their "observations cast doubt as to the direct effect of anti-ganglioside antibody induced neurological and pathological disorders." *Id.* (quoting Resp't's Ex. A, Tab 9 at 1).

Dr. Kedl further states that "[b]esides the alleged immunological target involved, the use of an adjuvant is always a key component of any argument in favor of vaccine-induced pathology via molecular mimicry." *Id.* Dr. Kedl notes that "[b]eing the inflammation-inducing component of the vaccine, the adjuvant is always implicated as creating the conditions necessary for the induction of autoimmune-mediated neuropathology." *Id.* Dr. Kedl continues that "all clinically relevant data fail to support this claim, especially in regards to the seasonal flu vaccine received by [Petitioner]." *Id.* Further noting the "excessive and chronic inflammatory conditions" in studies able to induce neuropathology, including repeated administrations of CFA over periods of months, Dr. Kedl asserts that "[t]he degree to which it is dissimilar to any clinically relevant vaccine, but most specifically, [Petitioner's] vaccine, cannot even be calculated." *Id.* at 5–6. Furthermore, he notes that although Dr. Haubner references adjuvant-containing flu vaccines, Petitioner received a "typical seasonal [flu] vaccine[, which] does not utilize the addition of any adjuvant, even alum." *Id.* at 6 (citing https://www.vaccinesafety.edu[92]). Though he denies evidence of a correlation between adjuvants (besides CFA) and neuropathology, Dr. Kedl asserts that "[r]eferences specific to the adjuvanted vaccine formulations are . . . irrelevant." *Id.*

Furthermore, Dr. Kedl states that, in regard to Petitioner's neuropathology, there is a "complete lack of evidence [of] any overt autoimmune involvement[.]" *Id.* at 5. He continues that Petitioner's "blood work, from before [November 7, 2013,] and onward, indicate no adversely elevated immune parameters other than a mono-gammopathy of undetermined significance that is clearly unrelated to his vaccine status." *Id.* He notes that "the only abnormalities found were related to thyroid, liver and metabolic function, all further indicators of a chronically deteriorating health status, but not of an acute immune-related event." *Id.*

Dr. Kedl continues that, contrary to Dr. Haubner's assertions, "[t]here is no accepted association between flu vaccination and autoimmunity." *Id.* at 6. He states that the articles Dr.

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[90] Adi Hersalis Eldar & Joab Chapman, *Guillain Barre Syndrome and Other Immune Mediated Neuropathies: Diagnosis and Classification*, 13 AUTOIMMUN. REV. 525 (2014)

[91] Somsankar Dasgupta et al., *Lack of Apparent Neurological Abnormalities in Rabbits Sensitized by Gangliosides*, 29 NEUROCHEM. RES. 2147 (2007).

[92] The link to the table Dr. Kedl refers to as of the issuance of this Decision is https://www.vaccinesafety.edu/Components-Excipients%2021-0115.pdf. Because the table is updated, the link provided by Dr. Kedl is no longer usable.

Haubner uses to support a relationship between flu vaccines and GBS/neuropathy "fail to fully support his assertion." *Id.* Dr. Kedl notes that authors of some of the articles cited by Dr. Haubner did not find associations between the adverse events and the iterations of flu vaccines studied. *Id.* (citing Pet'r's Ex. 21, ECF No. 83-1;[93] Pet'r's Exs. 27, 30). Additionally, Dr. Kedl avers that Dr. Haubner's references to articles focused on inflammatory neuropathies are not relevant because Petitioner "was not diagnosed with, nor did he have at any time, GBS, despite Dr. Haubner's arguments to the contrary." *Id.* at 7. Dr. Kedl further rejects Dr. Haubner's use of reviews and a case study "purporting to document support for an [ASIA]." In addition to documenting general problems with the ASIA theory, Dr. Kedl notes that "[t]o some extent, the entire argument is moot because . . . the seasonal flu vaccine received by [Petitioner] does not have [an adjuvant.]" *Id.* at 7–8.

Dr. Kedl also disagrees with Dr. Haubner's emphasis on the opinions of Petitioner's treating physicians, particularly Dr. Tracy's, to support a "logical sequence of causality[.]" *Id.* at 8. Noting that Dr. Tracy is a family practice physician, Dr. Kedl avers that "it is likely that Dr. Tracy has little more background, training or qualifications in immunology/vaccinology than does Dr. Haubner for drawing any larger conclusions regarding vaccines and idiopathic neuropathy." *Id.* He continues that Dr. Haubner, when discussing the opinions of Petitioner's treating providers, failed to consider that Dr. Nelson did not believe Petitioner's neuropathy was vaccine-related. *Id.* Dr. Kedl states that Dr. Nelson's position "is not surprising given that Dr. Nelson performed the nerve conduction studies on [Petitioner] and did not note any evidence to support the diagnosis of demyelinating neuropathy." *Id.* Dr. Kedl argues that "[i]f anything, conclusions of causation derived from [Petitioner's] treating physicians should probably be weighted toward Dr. Nelson, given his specialty and the nature of the tests [ ] he oversaw." *Id.* Dr. Kedl further emphasizes that "coincidence" does not equal "causality" and, accordingly, rejects Dr. Haubner's use of case reports as "unreliable relative to [ ] epidemiological studies . . . ." *Id.*

Dr. Kedl further disapproves of Dr. Haubner's "attempt[] to eliminate from consideration [Petitioner's] obviously deteriorating vascular, muscular, neurologic and emotional health." *Id.* Listing the conditions, including Petitioner's "myriad of medications, often taken at cross purposes [ ] prior to and since the onset of [Petitioner's] more overt neuropathy[]" that Dr. Haubner dismisses as non-disabling, Dr. Kedl states that "[t]he degree to which Dr. Haubner's assertions here contradict a rational, scientific approach to identifying a 'more than likely cause' of Petitioner's idiopathic neuropathy cannot be overstated." *Id.* at 9. Dr. Kedl continues that "[t]here is no form of responsibly practiced science or medicine in which all preexisting conditions are unilaterally dismissed in the attempts to construct an etiology or reach a diagnosis . . . One does not arrive at a viable scientific hypothesis by repeatedly asserting that relevant medical information can be 'dismissed as unrelated' unless one is already pre-committed to a specific outcome . . . ." *Id.*

Dr. Kedl rejects Dr. Haubner's characterization of Petitioner's condition in the days immediately following his vaccination as an "acute immune-mediated pathology[because]

[93] Enrique Alcade-Cabero et al., *Guillain-Barré syndrome following the 2009 pandemic monovalent and seasonal trivalent influenza vaccination campaigns in Spain from 2009 to 2011: outcomes from active surveillance by a neurologist network, and records from a country-wide hospital discharge database*, 16 BMC NEUROLOGY 75 (2016).

nothing in [Petitioner's] medical record agrees with that contention." *Id.* Dr. Kedl states that Petitioner's medical record does not contain "evidence of a demyelinating process" and that "no exacerbated immune involvement is apparent based on his blood work." *Id.* Dr. Kedl further avers that "[t]he development of an idiopathic neuropathy is perfectly consistent with the entirety of [Petitioner's] medical record, especially given the fact that [Petitioner] has multiple medical conditions that in and of themselves are more strongly associated with peripheral neuropathies than vaccination." *Id.* Dr. Kedl notes that adipose tissue is associated with peripheral neuropathies. *Id.* (citing Resp't's Ex. A, Tab 23[94]). He further notes that "[r]esearch is accumulating a list of risk factors for peripheral neuropathies that is striking for its overlap to numerous other aspects of [Petitioner's] medical condition." *Id.* Dr. Kedl states that "[a]ssociations with hypertension, dyslipidemia, and obesity have all been reported [ ]." *Id.* (citing Resp't's Ex. A, Tab 23 at 11 (noting that "independent associations with dyslipidemia and obesity have also been reported [ ])). He notes that Petitioner "had these medical issues and their accompanying risk factors for an extensive period of time prior to any vaccination event[]" and that "[t]he development of chronic peripheral neuropathies usually takes months to years to develop into overt clinical symptoms." *Id.* Dr. Kedl concludes that "[t]he appearance of [Petitioner's] neurological symptoms is thus far more consistent with the poor metabolic, nutritional and vascular health experienced by [Petitioner] for a prolonged time frame before his allegedly neuropathy-inducing vaccination event in October 2013." *Id.* He determines that "it is far more likely than not that [Petitioner] was well on the road towards an idiopathic neuropathy long before he encountered his seasonable [flu] vaccine, a vaccine which he had encountered yearly with no adverse reactions and, again, which contains no adjuvant to support and induction of acute inflammation." *Id.* at 10.

4. Respondent's Expert Report – Michael Wilson, M.D., M.A.S., F.A.A.N.

Dr. Michael Wilson is "a board-certified neurologist with subspecialty training in neuro-infectious diseases and neuroimmunology[]" and an "Associate Professor of Neurology at [the University of California, San Francisco ("UCSF") School of Medicine] in the Division of Neuroimmunology and Glial Biology . . . ." Resp't's Ex. C at 1, ECF No. 79-3; *see also* Resp't's Ex. D at 1, ECF No. 79-4. Dr. Wilson received his medical degree from UCSF in 2007. Resp't's Ex. D. at 1. He completed his residency in neurology in 2011 through the Harvard Neurology Residency Program at Massachusetts General Hospital and Brigham and Women's Hospital. *Id.* He subsequently completed a fellowship in neuro-infectious diseases at Massachusetts General Hospital in 2012. *Id.* Dr. Wilson also had postdoctoral fellowships in neurovirology and metagenomics at Boston University and UCSF, respectively. *Id.* He received his certification in neurology from the American Board of Psychiatry and Neurology in 2011 and has held teaching positions at both Boston University and UCSF. *Id.* at 2. Dr. Wilson began teaching as an assistant adjunct professor at UCSF in 2013. *Id.* He obtained clinical experience in neurology at various hospitals in Massachusetts between 2011 and 2013. *See id.* He has been an attending neurologist at UCSF Multiple Sclerosis and Neuroinflammation Center, where he conducts a "weekly half day clinic" and treats patients "with a variety of autoimmune and infectious diseases of the central nervous system[]" since 2013. *Id.* at 2, 4. Dr. Wilson is also the co-founder and co-director of the UCSF Precision Medicine Neuroinflammation Board, which focuses on "discuss[ion] and analy[sis of] challenging neuroinflammatory cases and research findings[]" and a co-founder of

[94] Rens Hanewinckel et al., *The Epidemiology and Risk Factors of Chronic Polyneuropathy*, 31 EUR. J. EPIDEMIOL. 5 (2016).

the UCSF Center Next-Gen Precision Diagnostics. *Id.* at 4. Dr. Wilson has received many awards, including multiple awards from the American Academy of Neurology. *Id.* at 3. His CV lists forty peer-reviewed publications as well as numerous abstracts and review articles. *See id.* at 14–21. Dr. Wilson is also "a Principal Investigator of a lab that has pioneered the development of metagenomic next-generation sequencing to diagnose neurologic infections in patients with meningitis, encephalitis and other neuroinflammatory conditions." Resp't's Ex. C at 1. His work has contributed to multiple publications as well as the "develop[ment of] comprehensive autoantibody and viral antibody discovery assays to search for antigenic targets and triggers of neuroinflammatory diseases . . . ." *Id.* Dr. Wilson's receives funding for his research from the National Institutes of Health, the National Multiple Sclerosis Society, and other foundations. *Id.*

Dr. Wilson states that Petitioner "certainly has peripheral neuropathy[]" but that there is no evidence that Petitioner has suffered from GBS or CIDP. *Id.* at 4–5. Dr. Wilson opines that Petitioner's "constellation of symptoms in the days and weeks after his [flu] vaccination (i.e., congestion, myalgias, headache, chills, no appetite, fatigue, and nausea) together with a grossly normal neurologic exam (including intact reflexes) at his November 7, 2013 primary care visit, is not consistent with GBS." *Id.* at 4. Regarding Petitioner's "comatose state" following his vaccination, Dr. Wilson notes that "[l]oss of consciousness can be associated with neuromuscular weakness and respiratory failure in the setting of GBS, but [Petitioner] would not have survived multiple days unattended with a compromised airway and simply gone to the doctor the next day with a grossly normal neurologic exam." *Id.* Dr. Wilson notes the possibility of encephalopathy associated with acute disseminated encephalomyelitis ("ADEM"),[95] "but again, this syndrome would not have self-resolved this quickly without treatment and supportive care." *Id.*

Dr. Wilson continues that Petitioner's "presentation is not consistent with a diagnosis of CIDP." *Id.* He notes that Petitioner's 2015 CSF examination was normal and that "it did not show the typical cyto-albuminologic dissociation found in GBS or CIDP." *Id.* Although Dr. Wilson notes that CSF testing is not required to diagnose GBS or CIDP, he states that "it can be very helpful in cases like [Petitioner's] in which a patient has multiple other co-morbidities that have resulted in pre-morbid peripheral nerve damage." *Id.* Dr. Wilson further points out that Petitioner "has not been found on serial neurologic exams to consistently have hypo- or areflexia and at times (including per [Dr. Haubner's] own admission), he has been found to have hyperreflexia in the lower extremities consistent with a myelopathy likely secondary to his degenerative disc disease and cervical spondylosis." *Id.* Additionally, Dr. Wilson avers that Petitioner's "two-month period of steroid-responsive forgetfulness more than a year after the vaccination is not consistent with any known adverse event from vaccinations." *Id.* at 5.

Dr. Wilson states that although he agrees with Petitioner that "there is extensive evidence of worsening mobility and functional status since 2013, [ ] it is also evident from the clinical documentation [ ] that the beginning of the decline preceded [Petitioner's] vaccination by multiple years[.]" *Id.* He continues that "there is no need to invoke a separate process for which there is inconsistent and incomplete evidence to understand why [Petitioner] has experienced progressive symptoms over the ensuing years." *Id.* He opines that, although Petitioner has submitted medical

[95] ADEM is "an acute or subacute encephalomyelitis or myelitis characterized by perivascular lymphocyte or mononuclear cell infiltration and demyelination[.]" *Acute Disseminated Encephalomyelitis*, DORLAND'S, https://www.dorlandsonline.com (last visited Oct. 21, 2021).

literature regarding "the known association between some vaccinations (including some [flu] vaccinations) and GBS or CIDP," Petitioner has not connected this literature to his own case. *Id.* Dr. Wilson states that "the fact that there has been no epidemiologic evidence provided to document that the 2013-2014 seasonal [flu] vaccine led to an increased risk of GBS despite the fact that very timely assessments can now be made of the safety profiles of influenza vaccines[]" reinforces his doubts. *Id.* Furthermore, noting Dr. Nelson and Dr. Becker's concerns regarding "a functional component to [Petitioner's] chronic symptoms and on his neurological exam (e.g., give way weakness)[,]" Dr. Wilson indicates that "it is hard to quantify to what degree [Petitioner's] mental health is contributing further to his disability." *Id.* In conclusion, Dr. Wilson states that some of the conditions Petitioner had prior to vaccination, including obesity, degenerative disc disease in the cervical and lumbar spine, bilateral CTS, and chronic opiate use, can "individually . . . cause neuropathic symptoms, but in combination, can synergistically make neuropathic symptoms worse and progressive." *Id.*

Regarding timing, Dr. Wilson opines that the years-long progression of Petitioner's symptoms is inconsistent with GBS, which involves symptoms that plateau after a twelve-hour to twenty-eight-day period of progression. *Id.* Although he notes that years-long progression may be consistent with CIDP, Dr. Wilson reasserts that the information in the record regarding Petitioner's reflexes and CSF profile does not indicate CIDP. *Id.* Dr. Wilson states that "[t]his is also the impression of the multiple neurologists who examined [Petitioner]." *Id.* Dr. Wilson notes that these conditions do not preclude inflammatory polyneuropathies such as GBS or CIDP but repeats that Petitioner's medical evidence is inconsistent with such diagnoses. *Id.* Dr. Wilson also remarks that, due to cost, Petitioner "has still not been able to get a complete work-up for all possible causes of his peripheral neuropathy including genetic etiologies and other inflammatory etiologies . . . ." *Id.* at 6.

III. Arguments in Support of and Against Entitlement

A. Petitioner's Motion for a Decision on the Record

In Petitioner's motion for a decision on the record, he argues that he has fulfilled the three *Althen* prongs. Regarding *Althen* prong one, Petitioner notes that the Program hears cases regarding what he states are "immune-mediated" neurological injuries and that demyelinating disease is a Table injury for flu vaccines. Pet'r's Mot. at 15–16. He continues that "[m]edical literature also supports the development of immune-mediated neurological disease after the [flu] vaccination." *Id.* at 16. Petitioner states that "[a]s this Court is well aware, the biological mechanism of molecular mimicry is thought to be the culprit." *Id.* at 17. In support of this proposition, Petitioner cites medical literature discussing "molecular similarity" between Campylobacter Jejuni ("C. jejuni") bacteria, infection with which is one of the most common conditions associated with GBS, and "GM1, one of the targets of autoantibodies in GBS patients[.]" *Id.* (citing Pet'r's Ex. 28). He notes that "Respondent's own expert cites to medical literature noting the causal connection between [flu] virus and demyelinating disease, and it states, '[m]ost cases are thought to result from an aberrant immune response triggered by a recent

infectious disease or vaccination.'" *Id.* at 17–18 (quoting Resp't's Ex. A, Tab 18[96]). Petitioner continues by identifying studies exploring the risk of GBS after influenza vaccinations. *Id.* at 18.

Petitioner argues that he has satisfied *Althen* prong two by demonstrating a logical sequence of cause and effect between his vaccination and injury. He asserts that he "had no diagnostic evidence of peripheral neuropathy prior to vaccination." *Id.* Although he admits to having preexisting health issues, including CTS and thyroid irregularities, Petitioner asserts that "[t]here is no question that something happened that dramatically changed the course of [his] health, and that 'something' is the [flu] vaccination." *Id.* Petitioner further claims that since his November 7, 2013 visit with Dr. Tracy, he "systematically sought medical care (probably as best he could given his work obligations, finances, and family obligations)." *Id.* at 19. Petitioner states that Dr. Tracy "considered an immune-mediated neuropathy as the medical records state 'no signs suggestive of [GBS] at this time.'" *Id.* (quoting Pet'r's Ex. 2 at 93).

Petitioner argues that although he "never had the acute 'crash' of an acute [GBS,] . . . the 2014 medical records document his increasingly worsening condition until the term 'peripheral neuropathy' is introduced into his medical chart on March 26, 2014." *Id.* Petitioner continues that he "consistently reported all of the insidious type symptoms that peripheral neuropathy can produce—numbness, tingling, feeling hot or cold, pain, weakness, and more." *Id.* Petitioner additionally notes that two of his "closest treating physicians have opined in this case in favor of vaccine causation." *Id.*

Petitioner argues that he has shown an adequate temporal relationship between his vaccination and injury in satisfaction of *Althen* prong 3 because his "decline in health began the week" post vaccination. *Id.* at 20. He notes that "[t]he Vaccine Injury Table recognizes a [three to forty-two] day window for the onset of GBS post[] influenza vaccination." *Id.* Petitioner admits that he "was diagnosed with peripheral neuropathy and not specifically with GBS (as, unfortunately, he did not undergo a lumbar puncture or EMG post vaccination within any time between October 2013 to January 2015)." *Id.* He maintains that "there is no question that this [P]rogram recognizes an onset of neurological disease within the timeframe of the onset of [Petitioner's] illness." *Id.*

Regarding alternative causes of Petitioner's peripheral neuropathy, Petitioner maintains that Respondent has not provided one outside of Respondent's argument that Petitioner's medical issues predated his vaccination. *Id.* at 21. Petitioner avers that this "is not supported by the medical chart." *Id.* Expanding on his pre-vaccination health, Petitioner states that "there were issues present, but none were debilitating." *Id.* at 2. He maintains that the "constellation of symptoms [he experienced post vaccination] was not present prior to his vaccination at issue." *Id.* at 4.

Petitioner also discusses the "[un]traditional" nature of the evidence he has presented, namely the "record review and report from his brother, [Dr. Haubner]." *Id.* at 15. Petitioner acknowledges that "[t]here is no question that a family member providing a report may raise a question of bias from the Special Master." *Id.* However, he asserts that Drs. Haubner, Becker, and Tracy "have gone on record here, at risk of their own reputations and careers . . . ." *Id.* He claims that the fact that none of these three doctors, "[u]nlike Respondent's experts," have been paid for their submissions "weighs heavily in favor of their credibility." *Id.* Regarding the strength of his

[96] Valerie Sivadon-Tardy et al., *Guillain-Barré Syndrome and Influenza Virus Infection*, 48 CLIN. INFECT. DIS. 769 (2013).

letters from treating physicians, Petitioner notes that "Dr. Becker is his treating neurologist . . . [, and] Dr, Tracy has been [Petitioner's treating physician for two decades." *Id.* He continues that Dr. Tracy's "opinion in this case directly answers the questions as to [Petitioner's] pre- and post-vaccination medical condition, as well as corroborating onset." *Id.*

B. Respondent's Response to Petitioner's Motion

Respondent begins his analysis by addressing the weight I should afford to Dr. Haubner's report. *See* Resp't's Resp. at 11. While noting that Respondent's experts "are highly credentialed and have extensive experience in the specific fields relevant to this case[,]" Respondent states that "[i]t is not clear how [Dr. Haubner's degree in pharmacology] qualifies him to opine on a case largely centered on neurology and immunology[.]" *Id.* at 11–12. Respondent continues that "[w]hile special masters in Vaccine Act proceedings need not exclude unreliable expert reports, the Court should afford Dr. Haubner's opinion 'but trifling probative weight.'" *Id.* (quoting *Veryzer v. Sec'y of Health & Hum. Servs.*, No. 06-522V, 2010 WL 2507791 at *22 (Fed. Cl. Spec. Mstr. June 15, 2010). Respondent asserts that this "trifling weight" is "based both on the potential for bias by submitting an expert report on behalf of one's brother, and because Dr. Haubner has poor qualifications to actually opine on the claim." *Id.*

Before exploring whether Petitioner has satisfied the *Althen* prongs, Respondent asserts that "Petitioner's claim must fail because the evidence establishes that his condition predated his vaccination." *Id.* at 13. He cites *W.C. v. Sec'y of Health & Hum. Servs.*, 704 F.3d 1352, 1357–58 (Fed. Cir. 2013) to support this proposition. *Id.* He notes that Petitioner has neither "pursued a significant aggravation claim . . . [nor] address[ed] any of the . . . factors required to prove such a claim." *Id.* at 13 n.4. Respondent avers that "[c]ontemporaneous medical records that establish a condition preexisted vaccination are entitled to presumptive reliability under the Vaccine Act." *Id.* at 13. Respondent continues that "the record establishes that [P]etitoner's condition predated his . . . vaccination[,]" noting that Petitioner had preexisting histories of multiple conditions and that Dr. Becker identified Petitioner's numbness and tingling as progressing since 2011. *Id.* at 14. Respondent further refers to his expert reports to suggest that Petitioner's preexisting conditions were signs of, and contributors to, his neuropathic symptoms. *See id.* at 14–15.

Discussing the *Althen* prongs, Respondent argues that Petitioner has not successfully presented a medical theory. *Id.* at 15. He notes that Dr. Haubner discusses conditions such as GBS, AIDP, and CIDP, as well as the ASIA concept and argues that Dr. Haubner "attempts to obfuscate the issue by inappropriately conflating these conditions with [P]etitioner's peripheral neuropathy." *Id.* He continues that "Dr. Haubner has provided no explanation for how GBS/AIDP or CIDP can be applied to this case and [P]etitioner's peripheral neuropathy. Instead, without reason, he conflates all of the conditions into some generalized neuropathy." *Id.* at 17.

Citing his expert reports and medical literature, Respondent continues that, regardless, "Dr. Haubner overstates the support in the literature for his theory, and has not shown that molecular mimicry is a reliable medical theory." *Id.* at 17–18. Respondent is further critical of Dr. Haubner's use of medical literature, arguing that "Dr. Haubner cite[s] several . . . articles for propositions that are not supported or are incomplete[]" and "relie[s] on studies discussing flu vaccines containing adjuvants . . . ." *Id.* at 18–19.

Respondent argues that Petitioner has failed to satisfy *Althen*'s second prong, because "[P]etitioner has not even shown that his peripheral neuropathy was immune-mediated." *Id.* at 20–

21. Although Respondent maintains that Petitioner's peripheral neuropathy predated his vaccination, he notes that, even if it arose post vaccination, Petitioner's "various comorbidities are relevant to whether it was the vaccine (and not his myriad other ailments) that caused his peripheral neuropathy." *Id.* at 21. Respondent avers that Petitioner's other conditions prevent him from being able to establish "that the vaccine was the actual cause under prong two of *Althen*." *Id.*

Respondent asserts that "[t]he statements from [P]etitioner's treating physicians fail to establish that the vaccine actually caused [P]etitioner's condition here." *Id.* He further notes that "the statements from [P]etitioner's treating physicians were not made contemporaneously with his treatment close-in-time to vaccination, but were instead made in contemplation of litigation." *Id.* at 22. Respondent refers to Dr. Becker's notes, which indicate that on June 8, 2015, Petitioner's lawyer wished to speak with Dr. Becker regarding this proceeding. *Id.* (citing Pet'r's Ex. 5 at 20). Respondent further argues that Dr. Becker's February 13, 2019 letter, in which Dr. Becker opined that Petitioner's vaccination "more likely than not significantly aggravated his condition[,]" should result in dismissal of this case because Petitioner did not pursue a significant aggravation claim. *Id.* (quoting Pet'r's Ex. 19 at 1). Respondent asserts that this letter further detracts from Petitioner's ability to satisfy *Althen* prong two because "Dr. Becker's note shows that he believed [P]etitioner's condition existed before the vaccine, but was worsened by it." *Id.*

Respondent further states that "[t]he remaining two statements from treating physicians[,]" the letter from Dr. Tracy and the opinions of Dr. Nelson documented in the medical records, "are equivocal[.]" *Id.* Respondent argues that "Dr. Tracy's conclusory assertion [of a logical sequence of cause and effect] appear to be based on timing alone," given Dr. Tracy's statement that the "timing would certainly fit . . . ." *Id.* at 23; Pet'r's Ex. 18 at 1. Further, Respondent continues that "this statement must be balanced against the opinion of Dr. Nelson," who did not believe Petitioner's neuropathy was vaccine-related. Resp't's Resp. at 23.

Denying that Petitioner has satisfied prong three, Respondent asserts "that the evidence establishes that [P]etitioner's condition predated his vaccination, and he therefore cannot show a medically acceptable causation." *Id.* Further, Respondent argues that "[P]etitioner's reference only to the GBS timeframe in the Vaccine Injury Table is legally insufficient to meet his burden . . . ." *Id.* Respondent quotes *Grant v. Sec'y of Health & Hum. Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992), which states that "[s]imple similarity to conditions or time periods listed in the Table is not sufficient evidence of causation [in an off-Table claim]." *Id.*

C. Petitioner's Reply

Petitioner contests Respondent's position that his condition predated his vaccination. Pet'r's Reply at 1. Petitioner notes that his preexisting conditions did not stop him from "work[ing] full[-]time in a demanding job and enjoy[ing] life." *Id.* at 1–2. He avers that "despite Dr. Kedl's opinion that [Petitioner] was just simply on this path toward a debilitating neuropathy, there is no question in this case that something dramatic happened . . . that precipitated a steep decline in health, and that this drastic change . . . occurred in close proximity to receipt of vaccination." *Id.* at 2 (emphases omitted). Petitioner states that he "changed from a functional individual with manageable health complaints to an individual suffering from progressive total body weakness[]" and other debilitating symptoms. *Id.* Petitioner claims that "[t]his was not present prior to vaccination." *Id.* He argues that his work calendar showing missed work in the days post vaccination demonstrates "the onset of [his] debilitating, new neurological symptoms." *Id.* Petitioner further maintains that his pre-vaccination medical conditions are unrelated to the

condition at issue. *Id.* He states that "[t]he signs and symptoms of plantar fasciitis pain, for example, and totally debilitating, full body weakness, diminished speech control, and diminished motor control will never reasonably look or feel anywhere close to the same by any reasonable person." *Id.* at 2–3.

Petitioner clarifies that he "does not allege that he has GBS, AIDP, or CIDP." *Id.* at 3. He states that Dr. Haubner references literature concerning those conditions because "the Vaccine Program has a history of cases with the influenza vaccination and demyelinating disease." *Id.* Petitioner claims that "Dr. Haubner merely discusses the established link between the [flu] vaccin[e] and neurological conditions. None of this information is novel or new to the Vaccine Program." *Id.*

In response to Respondent's concerns regarding Dr. Haubner's credentials, Petitioner notes that Dr. Haubner has "a medical background and training, and what he presented is not something the Vaccine program has never heard before." *Id.* He states that the purpose of Dr. Haubner's report was to "assist Petitioner's [c]ounsel and this Court in understanding what happened to Petitioner." *Id.* Petitioner maintains that Dr. Haubner cited to medical literature and that his "opinion as to what happened . . . post[]vaccination is corroborated by" Drs. Becker and Tracy. *Id.*

Petitioner criticizes Respondent's treatment of Petitioner's treating physician's statements, stating that Drs. Becker and Tracy "have given unequivocal opinions that [Petitioner] suffered an adverse response to vaccination leading to his current condition. By far, [they] are medical professionals with the most relevant and intimate knowledge of the medical evidence in" this case. *Id.* at 4. Petitioner further argues that, even though Dr. Tracy is a primary care physician, Dr. Tracy's longstanding and firsthand knowledge of Petitioner places him "in a better position than a paid expert . . . to author a letter regarding this case[.]" *Id.* at 5. Furthermore, Petitioner, noting that Dr. Kedl referred to Petitioner by an incorrect name at one point in his report, questions Dr. Kedl's credibility and characterizes his opinions as "appear[ing] to be a copied-and-pasted version of a previous report that must have been similarly worded and/or structured[.]" *Id.*

Petitioner disagrees with Dr. Kedl's emphasis on the lack of epidemiological studies and mass immunization campaigns because epidemiological studies are not required in the program, and "vaccine adverse events are so rare that studies like the ones referenced by Dr. Kedl lack the statistical power to detect such rare events." *Id.* Petitioner further avers that "population statistics are totally irrelevant when evaluating any one case." *Id.*

IV. Legal Standard Overview

To receive compensation under the Vaccine Act, a petitioner must demonstrate either that: (1) the petitioner suffered a "Table injury" by receiving a covered vaccine and subsequently developing a listed injury within the timeframe prescribed by the Vaccine Injury Table set forth at 42 U.S.C. § 300aa-14, as amended by 42 C.F.R. § 100.3; or (2) that petitioner suffered an "off-Table injury," one not listed on the Table, as a result of his receiving a covered vaccine. *See* 42 U.S.C. §§ 300aa-11(c)(1)(C); *Moberly v. Sec'y of Health & Hum. Servs.*, 592 F.3d 1315, 1321 (Fed. Cir. 2010); *Capizzano v. Sec'y of Health & Hum. Servs.*, 440 F.3d 1317, 1319-20 (Fed. Cir. 2006). Petitioner does not allege a Table injury in this case. Thus, he must prove either that his injury was caused-in-fact by a Table vaccine or that a preexisting injury was significantly aggravated by a Table vaccine.

To establish causation-in-fact, a petitioner must demonstrate by a preponderance of the evidence that the vaccine was the cause of the injury. 42 U.S.C. § 300aa-13(a)(1)(A). A petitioner is required to prove that the vaccine was "not only a but-for cause of the injury but also a substantial factor in bringing about the injury." *Moberly*, 592 F.3d at 1321–22 (quoting *Shyface v. Sec'y of Health & Hum. Servs.*, 165 F.3d 1344, 1352–53 (Fed. Cir. 1999)).

In the seminal case of *Althen v. Sec'y of the Dept. of Health & Hum. Servs*, the Federal Circuit set forth a three-pronged test used to determine whether a petitioner has established a causal link between a vaccine and the claimed injury. *See* 418 F.3d at 1278–79. The *Althen* test requires petitioners to set forth: "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." *Id.* at 1278. To establish entitlement to compensation under the Program, a petitioner is required to establish each of the three prongs of *Althen* by a preponderance of the evidence. *See id.*

If a petitioner argues that a vaccination did not cause-in-fact but instead significantly aggravated a preexisting injury or condition, the evidentiary burden is expanded. *See Loving v. Sec'y of Health and Hum. Servs.*, 86 Fed. Cl. 135, 144 (2009). The Vaccine Act defines significant aggravation as "any change for the worse in a preexisting condition which results in markedly greater disability, pain, or illness accompanied by substantial deterioration of health." § 300aa-33(4). In *Loving*, the Court set forth a six-factor test, which requires establishing the following:

> (1) the person's condition prior to administration of the vaccine, (2) the person's current condition (or the condition following the vaccination if that is also pertinent), (3) whether the person's current condition constitutes a "significant aggravation" of the person's condition prior to vaccination, (4) a medical theory causally connecting such a significantly worsened condition to the vaccination, (5) a logical sequence of cause and effect showing that the vaccination was the reason for the significant aggravation, and (6) a showing of a proximate temporal relationship between the vaccination and the significant aggravation.

Loving, 86 Fed. Cl. at 144.

Whether a petitioner's claim is analyzed as causation-in-fact or significant aggravation is generally determined by a petitioner's allegations. *See* § 300aa-11(a)(1) ("A proceeding for compensation under the Program for a vaccine-related injury or death shall be initiated by . . . the filing of a petition containing the matter prescribed by subsection (c) . . . ."); *see also* § 300aa-11(c)–(c)(1)(C)(ii)(I) ("A petition for compensation under the Program for a vaccine-related injury or death shall contain[] . . . an affidavit, and supporting documentation, demonstrating that the person who suffered . . . injury . . . sustained, or had significantly aggravated, any illness, disability, or condition caused by [a covered vaccine.]"). In this case, Petitioner expressly denies that his peripheral neuropathy predated his vaccination. Pet'r's Reply at 1. Thus, in order to establish entitlement to compensation, Petitioner must establish that his 2013 flu vaccination caused-in-fact his injury.

V. Discussion

A. Weight of Untraditional Opinion Evidence

Due to the unusual nature of some of the opinion evidence in the record, I find it necessary to determine the appropriate weight to give such evidence before discussing the *Althen* prongs. Although he was ordered to file an expert report, Petitioner filed a report authored by his brother, a Ph.D. of pharmacology. In addition to criticizing the substance of Dr. Haubner's report, Respondent contests that Dr. Haubner's report should be afforded any more than "trifling weight." Resp't's Resp. at 12. Petitioner acknowledges that Dr. Haubner's report "may raise a question of bias[]" but maintains that Dr. Haubner, along with Petitioner's treating physicians, has not been paid and "ha[s] gone on record here, at risk of [his] own reputation[] and career[] . . . ." Pet'r's Mot. at 15. Petitioner notes that Dr. Haubner has "a medical background and training[]" and that he cites medical literature, and Petitioner asserts that Dr. Haubner's opinion is "corroborated by" Petitioner's treating physicians. Pet'r's Reply at 3.

The Supreme Court's opinion in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), requires that courts determine the reliability of an expert opinion before it may be considered as evidence. "In short, the requirement that an expert's testimony pertain to 'scientific knowledge' establishes a standard of evidentiary reliability." *Id.* at 590 (citation omitted). Thus, for Vaccine Act claims, a "special master is entitled to require some indicia of reliability to support the assertion of the expert witness." *Moberly*, 592 F.3d 1315 at 1324. The Daubert factors are used in the weighing of the reliability of scientific evidence proffered. *Davis v. Sec'y of Health & Hum. Servs.*, 94 Fed. Cl. 53, 66-67 (2010) ("[U]niquely in this Circuit, the *Daubert* factors have been employed also as an acceptable evidentiary-gauging tool with respect to persuasiveness of expert testimony already admitted[.]"). When both sides offer expert testimony, a special master's decision may be "based on the credibility of the experts and the relative persuasiveness of their competing theories." *Broekelschen v. Sec'y of Health & Hum. Servs.*, 618 F.3d 1339, 1347 (Fed. Cir. 2010) (citing *Lampe v. Sec'y of Health & Hum. Servs.*, 219 F.3d 1357, 1362 (Fed. Cir. 2000)). And nothing requires the acceptance of an expert's conclusion "that is connected to existing data only by the ipse dixit of the expert[,]" especially if "there is simply too great an analytical gap between the data and the opinion proffered." *Snyder v. Sec'y of Health & Hum. Servs.*, 88 Fed. Cl. 706, 743 (2009) (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997)).

The Federal Circuit has clearly stated that special masters, as finders of fact, "are entitled—indeed, expected—to make determinations as to the reliability of the evidence presented to them and, if appropriate, as to the credibility of the persons presenting that evidence." *Moberly*, 592 F.3d at 1326. When assessing the reliability of expert testimony, special masters may consider factors such as "the qualifications, training, and experience of the expert witnesses; the extent to which their proffered opinions are supported by reliable medical research and other testimony; and the factual basis for their opinions[.]" *Lehner v. Sec'y of Health & Hum. Servs.*, No. 08-554V, 2015 WL 5443461, at *5 (Fed. Cl. Spec. Mstr. July 22, 2015) (citing *LaLonde v. Sec'y of Health & Hum. Servs.*, 746 F.3d 1334, 1340 (Fed. Cir. 2014)).

When determining the reliability of expert opinions, or determining the relative weight to give to competing opinions, special masters may consider whether the issues experts opine on are within their areas of expertise. *See Wyatt v. Sec' of Health & Hum. Servs.*, 825 Fed. Appx. 880, 886 (Fed. Cir. 2020) (holding that "the factual findings of the Special Master regarding GBS [were] not arbitrary and capricious[]" when, among other issues, "the Special Master determined that Dr. DeMio's expert testimony should be given little weight because Dr. DeMio has no specialized training in autoimmune or neurological disorders and had conducted no research in either field."). "This is most obviously necessary when an expert offers an opinion that plainly exceeds his

training or individual competence." *Hughes v. Sec'y of Health & Hum. Servs.*, No. 16-930V, 2021 WL 839092, at *24 (Fed. Cl. Spec. Mstr. Jan. 4, 2021). Indeed, special masters have previously deemed opinion evidence unreliable due to an expert's lack of pertinent qualifications. *See R.K. v. Sec'y of Health & Hum. Servs.*, No. 03-0632V, 2015 WL 10936124, at *118 (Fed. Cl. Spec. Mstr. Sept. 28, 2015) ("Doctor Deth's medical opinions regarding A.K.'s gastrointestinal inflammation and its purported relationship to two vaccinations were outside his expertise and unsupported by other evidence. I find them inherently unreliable based on Dr. Deth's lack of qualifications to diagnose this child and to opine on the cause of a neurodevelopmental condition."); *Fresco v. Sec'y of Health & Hum. Servs.*, No. 06-469V, 2013 WL 364723, at *26 (Fed. Cl. Spec. Mstr. Jan. 7, 2013) ("[Dr.] Buttram and his report barely pass the very generous standards applied in Vaccine Act cases in favor of hearing nearly any evidence a party submits . . . His 'board certification' in environmental medicine does not qualify him to opine on the causes of autism, . . . particularly in the absence of any training or research credentials in the field of neurology or neurological disorders in children.").

Special masters may also consider an expert's bias when considering how to weigh testimony. In a previous case in which a petitioner's counsel called the counsel's mother as an expert witness, the presiding special master stated that "[f]amilial relationships alone may raise the issue of bias." *Miller v. Sec'y of Health & Hum. Servs.*, No. 02-235V, 2015 WL 5456093, at *11–12 (Fed. Cl. Spec. Mstr. Aug. 18, 2015). The special master continued that the doctor's "poor qualifications to opine as an expert and her familial relationship to petitioner's counsel do not preclude her appearance as a witness under the more flexible evidentiary standards in effect in Vaccine Act cases but both bear on the weight accorded to her testimony." *Id.* at *12. Although a special master may exclude unreliable evidence, especially when ruling on a motion to exclude, a special master may "err on the side of admitting predominantly unreliable opinion evidence, but then [] afford it but trifling probative weight." *Veryzer*, 2010 WL 2507791, at *22.

Petitioner never refers to Dr. Haubner as an "expert." However, Petitioner's decisions to submit Dr. Haubner's CV, to submit Dr. Haubner's review in lieu of a traditional expert report, and to reference his "medical background and training" make it clear that Petitioner is relying on Dr. Haubner's education and experience in pharmacology to give weight to his opinions and review of the case. Because Dr. Haubner is assuming a role in this case that is typically reserved for expert witnesses, I will evaluate the reliability of his opinions and analyses as I would evaluate those of an expert. Petitioner has not demonstrated that Dr. Haubner's qualifications rise to the level necessary to render his testimony persuasive. Previous cases have made it clear that special masters may discount medical opinions from individuals who lack education and/or experience in the specific fields at issue. Furthermore, Program experts typically have significant experience with the injuries or vaccine processes at issue.

Dr. Haubner's CV indicates that he completed his Ph.D. in pharmacology in 2008. All but two of his listed publications predate 2006. Although pharmacology is the study of drugs,[97] it is not clear that any of Dr. Haubner's work, research, or study pertained to vaccines or any issue related to this case. For instance, of his six publications, three concern nicotinic receptors and rat striatum,[98] and the other three are entitled "Novel antiepileptic and anticonvulsive therapeutic

[97] *See supra* note 76.

[98] The publications are entitled "N-n-alkylnicotinium analogs, a novel class of nicotinic receptor antagonist: inhibition of S(-)-nicotine-evoked [(3)H]dopamine overflow from superfused rat striatal

agents[,]" "Substitutions in hamster CAD carbamoyl-phosphate synthetase alter allosteric response to 5-phosphoribosyl-alpha-pyrophosphate (PRPP) and UTP[,] and "Improving the inhibitory activity of arylidenaminoguanidine compounds at the N-methyl-D-aspartate receptor complex from a recursive computational-experimental structure-activity relationship study." Pet'r's Ex. 16 at 2–3. These titles do not indicate that the articles relate to vaccines. Additionally, it does not appear that Dr. Haubner has held any professional position in pharmacology or a related field since his postdoctoral position in or around 2007. It is unclear what, if anything, Dr. Haubner has done over the past ten years relating to pharmacology. His CV indicates that he earned an MBA between 2012 and 2017 but does not indicate any activity in pharmacology during this time frame. Other than being listed as an author on a paper published in 2013, it does not appear that Dr. Haubner has worked in or studied pharmacology since he earned his Ph.D. in 2008.

Furthermore, Dr. Haubner spends portions of his "review and report" discussing Petitioner's pre- and post-vaccination medical conditions as well as the relationships between such conditions. The record contains no evidence that Dr. Haubner has education or experience related to the diagnosis of, progression of, or interaction between peripheral neuropathies or neuropathies and the other conditions Petitioner experienced. Further, it is unclear that anyone whose training is limited to pharmacology or a related field would be able to offer persuasive testimony on causes of, or relationships between, diseases or conditions. *See McGuire v. Sec'y of Health & Hum. Servs.*, No. 10-609V, 2015 WL 6150598, at *11–12 (Fed. Cl. Spec. Mstr. Sept. 28, 2015) (determining that the testimony regarding causes of disease from a clinical pharmacist whose doctorate of pharmacy involved study of pharmacology "was not very helpful[]"). Dr. Haubner also has not provided medical literature to support his assertions regarding Petitioner's peripheral neuropathy and overall condition. I will therefore give little, if any, weight to Dr. Haubner's analysis pertaining to Petitioner's medical conditions.

In light of the relaxed evidentiary standards in this Program and Petitioner's request for a ruling on the current record, I will consider Dr. Haubner's report in my analysis. His CV indicates minimal qualifications to opine in this case, but I do not find that his qualifications, training, and experience are sufficient indicia of reliability to support persuasive testimony. I will consider Dr. Haubner's statements and conclusions commensurate with his qualifications and award his opinions only trifling weight.

B. *Althen* Analysis

1. *Althen* Prong One

Under the first prong of *Althen*, a petitioner must offer a scientific or medical theory that answers in the affirmative the question: "can the vaccine[] at issue cause the type of injury alleged?" *See Pafford v. Sec'y of Health & Hum. Servs.*, No. 01-0165V, 2004 WL 1717359, at *4 (Fed. Cl. Spec. Mstr. July 16, 2004), *aff'd*, 64 Fed. Cl. 19 (2005), *aff'd*, 451 F.3d 1352 (Fed. Cir. 2006). To satisfy this prong, a petitioner's theory must be based on a "sound and reliable medical or scientific explanation." *Knudsen*, 35 F.3d at 548; *see also Andreu v. Sec'y of Health & Hum. Servs.*, 569 F. 3d 1367, 1375, 1379 (2009) (ruling that the petitioners had satisfied *Althen* prong

slices[,]" "N-n-alkylpyridinium analogs, a novel class of nicotinic receptor antagonists: selective inhibition of nicotine-evoked [3H] dopamine overflow from superfused rat striatal slices[,]" and "The bis-picolinium salt, bPiDDB, I a potent and selective antagonist at nicotinic acetylcholine receptors mediating nicotine-evoked dopamine release in rat striatum." Pet'r's Ex. 16 at 2.

one where their expert witness had "presented a 'biologically plausible' theory"). Such a theory must only be "legally probable, not medically or scientifically certain." *Knudsen*, 35 F.3d at 548–49. However, as the Federal Circuit has made clear, "simply identifying a 'plausible' theory of causation is insufficient for a petitioner to meet her burden of proof." *LaLonde v. Sec'y of Health & Hum. Servs.*, 746 F.3d 1334, 1339 (Fed. Cir. 2014) (citing *Moberly*, 592 F.3d at 1322). Rather, "[a] petitioner must provide a reputable medical or scientific explanation that pertains specifically to the petitioner's case." *Moberly*, 592 F.3d at 1322. In general, "the statutory standard of preponderance of the evidence requires a petitioner to demonstrate that the vaccine more likely than not caused the condition alleged." *LaLonde*, 746 F.3d at 1339.

Petitioner can present a medical theory pursuant to prong one in a number of ways. "Reliability and plausibility of . . . pathogenesis can be bolstered by providing evidence that at least a sufficient minority in the medical community has accepted the theory, so as to render it credible." *Id.* Additionally, "epidemiological studies and an expert's experience, while not dispositive, lend significant credence to the claim of plausibility." *Id.* Medical literature published in respected medical journals is also persuasive. *Id.* "However, publication 'does *not* necessarily correlate with reliability', because 'in some instances well-grounded but innovative theories will not have been published.'" *Id.* (quoting *Daubert*, 509 U.S. at 593–94 (emphasis in original)).

Petitioner alleges molecular mimicry is a biological mechanism linking the flu vaccine and peripheral neuropathy. Petitioner claims that "[a]t this time there remains little doubt that a vaccine-induced antibody's non-specific cross reactivity with native tissues is the major mechanistic basis and is a cause of a vaccine-related autoimmune diseases like that suffered by [ ] Petitioner." Pet'r's Ex. 15 at 5. In support of his theory, Petitioner has filed numerous articles and reports, but those papers fail to adequately explain how a seasonal flu vaccine can cause peripheral neuropathy.[99]

For example, Petitioner submitted Segal and Shoenfeld's paper explaining the concept of molecular mimicry as well as the role of adjuvants. Although it provides useful background on molecular mimicry generally, the authors do not discuss the relationship between molecular mimicry and seasonal flu vaccines. Rather, they discuss H1N1 vaccines administered around the 2009 influenza pandemic. The most prevalent of those vaccines involved an adjuvant. *See* Pet'r's Ex. 28 at 6. Dr. Kedl, however, notes that "the typical seasonal [flu] vaccine used in the [United States] does not utilize the addition of any adjuvant, even alum." Resp't's Ex. A at 6. Dr. Kedl thus argues that "[r]eferences specific to the adjuvanted vaccine formulations are therefore irrelevant[.]" *Id.* In support of this assertion, Dr. Kedl cites the Vaccine Excipients table published by www.vaccinesafety.edu. Although the table is updated and does not directly indicate whether excipients differ between seasonal flu vaccines depending on the year, the table indicates that adjuvants are not used in seasonal flu vaccines. Additionally, Petitioner has provided no evidence that the vaccine he received contained an adjuvant. In light of Dr. Kedl's expertise and Petitioner's

[99] While the undersigned has reviewed all of the information filed in this case, only those filings and records that are most relevant to the decision will be discussed. *Moriarty v. Sec'y of Health & Hum. Servs.*, 844 F.3d 1322, 1328 (Fed. Cir. 2016) ("We generally presume that a special master considered the relevant record evidence even though he does not explicitly reference such evidence in his decision.") (citation omitted); *see also Paterek v. Sec'y of Health & Hum. Servs.*, 527 F. App'x 875, 884 (Fed. Cir. 2013) ("Finding certain information not relevant does not lead to—and likely undermines—the conclusion that it was not considered.").

failure to demonstrate that he received an adjuvanted vaccine, I find that medical literature specifically pertaining to the role of adjuvants in molecular mimicry or adjuvant-containing vaccines does not aid Petitioner in establishing a medical theory pursuant to prong one.[100]

Petitioner also filed a review by Chavada and Willison. There is nothing in this paper that explains how a seasonal flu vaccine could cause peripheral neuropathy via molecular mimicry. Dr. Haubner claims this paper "catalogs numerous instances over the prior [twenty-five] years where autoantibodies directed against native tissue, have caused neuropathies." Pet'r's Ex. 15 at 2. He continues that "[t]his research confirms that '[b]asic studies continue to support a direct role for autoantibodies in neuropathy pathogenesis.'" *Id.* (quoting Pet'r's Ex. 24 at 1). Dr. Kedl, however, rejects Petitioner's characterization of the article. *See* Respt'r's Ex. A at 4. Dr. Kedl states that "the authors . . . emphasized the potential usefulness of glycan-reactive antibodies as potential biomarkers of disease, and only speculat[ed] as to their possible, but as of yet unproven role in pathology." *Id.*

Dr. Kedl notes that Chavada and Willison "even go as far as to state that no reliable immune targets have been found for AIDP and CIDP, the inflammatory neuropathies most often alluded to by Dr. Haubner." *Id.* Indeed, Dr. Haubner alludes to CIDP and AIDP in his review of Petitioner's claim, but the record does not contain evidence that Petitioner suffered from either of these conditions. Dr. Becker discussed the possibility of CIDP with Petitioner on February 5, 2015. Pet'r's Ex. 5 at 33. However, Dr. Becker did not continue to pursue or discuss this possibility, and there is no evidence that Petitioner obtained the sural nerve biopsy Dr. Becker recommended. Furthermore, Dr. Wilson opines that Petitioner's presentation is inconsistent with CIDP as well as GBS.

The authors specifically note that "evidence continues to emerge supporting the hypothesis that the pathophysiology of GBS is an antibody-mediated disorder driven in part by molecular mimicry with microbial products." *Id.* at 2. However, the record does not evidence that Petitioner had GBS, Petitioner has not claimed that he suffered from GBS, and Petitioner has not demonstrated that his condition is analogous to GBS. Further, as Dr. Kedl indicated, not all neuropathies have the same etiology, and an idiopathic peripheral neuropathy would not be inflammatory or demyelinating. Furthermore, Chavada and Willison do not provide an explanation for how any of the various antibodies discussed throughout their paper could be related to flu vaccines.

Chavada and Willison's review is too broad in scope to clarify Petitioner's medical theory. It establishes that AGAbs have been found in some patients with miscellaneous neuropathies, but it does not provide even a general explanation for how those antibodies could be related to the flu vaccine or a relationship between the flu vaccine and peripheral neuropathy. Furthermore, Petitioner's reliance on this article does not account for Dr. Kedl's assertion that "as those well versed in immunology are familiar with, simple detection of antibodies reacting with self-antigens

[100] Furthermore, the validity of the ASIA theory has been repeatedly called into doubt in the Program. *See, e.g.*, *D'Angiolini v. Sec'y of Health & Hum. Servs.*, 122 Fed. Cl. 86, 102 (2015) (upholding the special master's "determin[ation] that ASIA does not provide[] a biologically plausible theory for recovery"), *aff'd,* 645 Fed. Appx. 1002 (Fed. Cir. 2016); *Garner v. Sec'y of Health & Hum. Servs.*, No. 15–063V, 2017 WL 1713184, at *8 (Fed. Cl. Spec. Mstr. Mar. 24, 2017) (observing that the ASIA theory "is, at a minimum, incomplete and preliminary—and therefore unreliable from an evidentiary standpoint").

is an unreliable indicator of autoimmunity. Indeed, antibodies against self-antigens can be found in all healthy individuals." Resp't's Ex. A at 4.

The other pieces of medical literature Petitioner provided also do not aid him in satisfying prong one. While the Schattner article discussed research regarding links between flu vaccines and GBS, among links between other vaccines and conditions, it is unclear how this contributes to Petitioner's theory. As previously stated, Petitioner has not claimed that he suffered from GBS, and Dr. Wilson has explained that Petitioner's condition is inconsistent with GBS. Petitioner filed a few other articles exploring links between GBS and flu vaccines which similarly do not contribute to Petitioner's satisfaction of prong one. Petitioner references the Table's acknowledgement that flu vaccines can cause GBS, *see* Pet'r's Ex. 15 at 4–5, but, again, Petitioner has not alleged, and the record does not indicate, that he suffered from GBS. Petitioner further submitted additional articles pertaining to ASIA or adjuvanted flu vaccines, which do not contribute to his case for reasons discussed above.

Ultimately, in order to successfully pursue a causation-in-fact claim, Petitioner must satisfy his burden to present a medical theory linking the vaccine he received with the injury he suffered. A petitioner is not required to articulate a specific biological mechanism, but in this case, Petitioner has not provided even a general explanation for how a seasonal flu vaccine might, through molecular mimicry, cause a non-specific peripheral neuropathy. This starkly contrasts with cases in which petitioners have successfully utilized molecular mimicry to satisfy prong one. Indeed, "[p]etitioners cannot simply invoke the concept of molecular mimicry and call it a day." *Sheets v. Sec'y of Health & Hum. Servs.*, No. 16-1173V, 2019 WL 2296212, at *17 (Fed. Cl. Spec. Mstr. Apr. 30, 2019) (determining that a petitioner had not satisfied prong one when he did not relate molecular mimicry "to either the vaccines in question or [the p]etitioner's own specific condition."). Rather, they need to offer *reliable* and *persuasive* medical or scientific evidence of some kind (whether expert testimony or literature) that suggests" that the mechanism alleged could occur. *Johnson v. Sec'y of Health & Hum. Servs.*, No. 14-254V, 2018 WL 2051760, at *26 (Fed. Cl. Spec. Mstr. Mar. 23, 2018).

Petitioner has "invoke[d] the concept of molecular mimicry." However, he has not explained, even in general terms, how a seasonal flu vaccine could interact with or introduce AGAbs or other components. He has not explained how said components, if present, could result in the general neuropathy suffered by Petitioner. I find that Petitioner has presented insufficient evidence to satisfy *Althen* prong one.

2. *Althen* Prong Two

Under the second prong of *Althen*, a petitioner must prove that the vaccine actually did cause the alleged injury in a particular case. *See Pafford*, 2004 WL 1717359, at *4; *Althen*, 418 F.3d at 1279. The second *Althen* prong requires proof of a logical sequence of cause and effect, usually supported by facts derived from a petitioner's medical records. *Althen*, 418 F.3d at 1278; *Andreu*, 569 F.3d at 1380; *Capizzano*, 440 F.3d at 1326; *Grant*, 956 F.2d at 1148. A petitioner does not meet this obligation by showing only a temporal association between the vaccination and the injury; instead, the petitioner "must explain *how* and *why* the injury occurred." *Pafford*, 2004 WL 1717359, at *4 (emphasis in original). The Court in *Pafford* noted petitioners "must prove [ ] both that her vaccinations were a substantial factor in causing the illness . . . and that the harm would not have occurred in the absence of the vaccination." *Id.* (citing *Shyface*, 165 F.3d at 1352). Nevertheless, "[r]equiring epidemiologic studies . . . or general acceptance in the scientific or

medical communities . . . impermissibly raises a claimant's burden under the Vaccine Act and hinders the system created by Congress . . . ." *Capizzano*, 440 F.3d at 1325–26.

When considering whether a petitioner has fulfilled this prong, special masters determine whether the record shows, by a preponderance of the evidence, that a petitioner's injury was actually caused by the vaccine in question. "There may well be a circumstance where it is found that a vaccine *can* cause the injury at issue and where the injury was temporally proximate to the vaccination, but it is illogical to conclude that the injury was actually caused by the vaccine." *Capizzano*, 440 F.3d at 1327. A special master may deny that a petitioner has fulfilled the second prong "when medical records and medical opinions do not suggest that the vaccine caused the injury, or where the probability of coincidence or another cause prevents the claimant from proving the vaccine caused the injury by a preponderance of the evidence." *Id.*

The Federal Circuit has stated that "treating physicians are likely to be in the best position to determine whether 'a logical sequence of cause and effect show[s] that the vaccination was the reason for the injury.'" *Id.* at 1326 (quoting *Althen*, 418 F.3d at 1280). Thus, testimony from treating physicians is "quite probative." *Andreu*, 569 F.3d at 1375 (quoting *Capizzano*, 440 F.3d at 1326). However, "there is nothing . . . that mandates that the testimony of a treating physician is sacrosanct—that it must be accepted in its entirety and cannot be rebutted." *Snyder v. Sec'y of Health & Hum. Servs.*, 88 Fed. Cl. 706, 746 n.67 (2009). A special master may consider the bases of treating physicians' opinions and weigh the opinions against conflicting evidence, including opinions of other treating physicians. *See Hibbard v. Sec'y of Health & Hum. Servs.*, 100 Fed. Cl. 742, 749 (2009) (indicating that a special master's decision to weigh opinions of treating physicians against records from other treating physicians was not arbitrary or capricious).

In addition to opinions of treating physicians, contemporaneous medical records are favored in the Program. *See Capizzano*, 440 F.3d at 1326. In Program cases, "[m]edical records, in general, warrant consideration as trustworthy evidence." *Cucuras v. Sec'y of Health & Hum. Servs.*, 933 F.2d 1525, 1528 (Fed. Cir. 1993). Indeed, contemporaneous medical records are ordinarily to be given significant weight due to the fact that "the records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events." *Id.* However, there is no "presumption that medical records are accurate and complete as to all of the patient's physical conditions." *Kirby v. Sec'y of Health & Hum. Servs.*, 997 F.3d 1378, 1383 (Fed. Cir. 2021) (finding that a special master must consider the context of a medical encounter before concluding that it constitutes evidence regarding the absence of a condition.). While a special master must consider the presented medical opinions and records, they are not "binding on the special master or court." 42 U.S.C. § 300aa-13(b)(1). Rather, when "evaluating the weight to be afforded to any such . . . [evidence], the special master . . . shall consider the entire record . . . ." *Id.*

Petitioner has not established a logical sequence of cause and effect between his vaccination and peripheral neuropathy. Petitioner has not presented a medical theory by which I can evaluate whether Petitioner's vaccination in fact caused his injury. Since Petitioner has invoked molecular mimicry, however, I will begin by addressing that. Molecular mimicry, and much of Petitioner's argument regarding it, pertains to autoimmune processes. Yet, as Respondent asserts, Petitioner has not "shown that his peripheral neuropathy was immune-mediated." Resp't's Resp. at 20. As Respondent notes, Dr. Kedl observes a "complete lack of evidence for any overt

autoimmune involvement in [Petitioner's] neuropathology. Indeed, his blood work, from before [November 7, 2013,] and onward, indicates no adversely elevated immune parameters other than a mono-gammopathy of undetermined significance that is clearly unrelated to his vaccine status." *Id.*; Resp't's Ex. A at 5. In addition to the IgM kappa monoclonal protein, Dr. Nelson found that Petitioner had an abnormal IgG result for FGFR3. Pet'r's Ex. 13 at 106; Pet'r's Ex. 6 at 3. Dr. Nelson stated that "[p]ossibly this antibody titer [(FGFR3)] is related to [Petitioner's] symptoms." Pet'r's Ex. 6 at 1. Dr. Nelson noted an association between FGFR3 antibodies and autoimmune disorders but later described Petitioner's FGFR3 antibodies as "likely [ ] unrelated to his problems . . . ." Pet'r's Ex. 13 at 12. The record overall does not contain preponderant evidence that Petitioner suffered from an autoimmune disorder. While Dr. Becker mentioned Hashimoto's disease and encephalopathy in Petitioner's medical records, Petitioner was never diagnosed with either of these conditions. Furthermore, there is no discussion by Dr. Becker that explains the applicability of either of these conditions to Petitioner's symptoms. Petitioner does not allege vaccine-caused Hashimoto's or encephalopathy. Regardless, the record does not evidence that any of Petitioner's providers believed his peripheral neuropathy stemmed from an autoimmune process. I find that Petitioner has not established by a preponderance of the evidence that he has an autoimmune disorder that contributed to his peripheral neuropathy. Petitioner has not shown either (1) that an autoimmune disorder or process was related to his peripheral neuropathy or (2) that there is any relationship between the flu vaccine and the antibodies found.

Furthermore, Respondent contends that Petitioner's peripheral neuropathy predated his vaccination and thus cannot have been caused-in-fact by his vaccination. Respondent cites *W.C. v. Sec'y of Health & Hum. Servs.*, in which the Federal Circuit declared that "[i]f a petitioner has a disorder before being vaccinated, the vaccine logically cannot have caused the disorder." 704 F.3d 1352, 1358 (Fed. Cir. 2013) ("The special master's finding that [a p]etitioner had multiple sclerosis before receiving the vaccine [at issue] means that [the p]etitioner did not establish a 'logical sequence of cause and effect showing that the vaccination was the reason for [the petitioner's] injury' as required by prong two of *Althen*."). Petitioner, however, maintains that his injury did not predate his vaccination, stating that he "was able to maintain a demanding job prior to vaccination[]" and that "[h]is preexisting health complaints . . . did not stop him from performing his job or living his life." Pet'r's Reply at 1. Petitioner asserts that he experienced new, severe symptoms post vaccination and maintains that his pre-vaccination issues are "unrelated" to his post-vaccination peripheral neuropathy. *See id.* at 2. In light of the entire record, I find that Petitioner has not established by a preponderance of the evidence that his peripheral neuropathy arose after his vaccination.

Although Petitioner has argued that his pre-vaccination symptoms are "unrelated" to his post-vaccination condition, he has not provided adequate support for this assertion or sufficient evidence that Dr. Haubner is qualified to evaluate Petitioner's medical conditions. Dr. Wilson, however, has stated that it is "evident from the clinical documentation [ ] that the beginning of the decline [in Petitioner's health] preceded [Petitioner's] vaccination by multiple years[.]" Resp't's Ex. C at 5. Furthermore, Dr. Wilson states that some of the conditions Petitioner had prior to vaccination can "individually . . . cause neuropathic symptoms, but in combination, can synergistically make neuropathic symptoms worse and progressive." *Id.*

Indeed, there are medical records that indicate onset of peripheral neuropathy prior to vaccination. For instance, when Petitioner presented to Dr. Becker on January 8, 2015, Dr. Becker noted that "[s]ince 2011, [Petitioner] had slowly progressive numbness and tingling pains in his arms and hands, greater than the feet." Pet'r's Ex. 5 at 37. On August 13, 2013, approximately two and a half months pre vaccination, Petitioner reported intermittent pain radiating from his neck to fingertips, and Dr. Tracy indicated there was "[n]o specific trauma." Pet'r's Ex. 2 at 96. On August 22, 2013, Petitioner told PT Walicki that he "had numbness in left arm to fingers" after being hit by waves at the beach. Pet'r's Ex. 7 at 32. Further, Petitioner had a history of pain in various body parts, including extremities, prior to vaccination.

Distinguishing between Petitioner's pre- and post-vaccination symptoms is further complicated by the fact that Petitioner's claim is based on a nonspecific neuropathy. Although there have been Program petitioners who have prevailed on such claims, that Petitioner's neuropathy is nonspecific makes it difficult to distinguish between his pre- and post-vaccination symptoms. He does not have a diagnosis that would indicate specific symptoms or a specific progression. Additionally, Petitioner's argument that his peripheral neuropathy postdated his vaccination primarily centers on the severity of his symptoms rather than the symptoms themselves. Petitioner has not presented preponderant evidence that his post-vaccination malaise was related to his neuropathy. Petitioner has not alleged, nor does the record suggest, that his memory or speech issues are symptoms of peripheral neuropathy. The medical records indicate that the main symptoms of his neuropathy, including extremity pain, numbness, and tingling, appeared prior to vaccination, albeit in less severe forms.

Petitioner has argued that the opinions of his treating physicians are entitled to great weight, and this position is supported by Program precedent. He relies heavily on the opinion of Dr. Tracy, asserting that his opinion clarifies Petitioner's pre- and post-vaccination conditions and corroborates a post-vaccination onset of symptoms. However, Drs. Becker and Tracy have raised the possibility that Petitioner's vaccination may have aggravated a preexisting condition rather than caused a new condition. Dr. Becker stated that "[a]lthough [Petitioner] experienced some minor pain in his arms and hands (greater than feet) from 2011 to 2013, his problems significantly *worsened* after" his 2013 flu vaccination. Pet'r's Ex. 19 (emphasis added). Dr. Becker further asserted that he "believe[s Petitioner's 2013 flu vaccination] more likely than not *significantly aggravated* his condition." *Id.* (emphasis added). Dr. Becker did not directly state in his letters that Petitioner had peripheral neuropathy prior to his vaccination, and he also stated that "[w]e will never know for sure what happened to [Petitioner]." *Id.* Although Dr. Becker did not specify whether he intended "condition" to refer to Petitioner's peripheral neuropathy or Petitioner's general health, Dr. Becker specifically noted that Petitioner experienced pain in his arms, hands, and feet prior to vaccination. *Id.* Petitioner experienced symptoms in these areas post vaccination that were attributed to his peripheral neuropathy. Further, Dr. Becker's choice of words indicates that Petitioner's post-vaccination condition was a continuation, or more severe iteration, of a preexisting issue. Dr. Tracy noted that Petitioner did not have a diagnosis of peripheral neuropathy prior to vaccination, but he also stated that "[w]e will never know for sure what caused [Petitioner's] peripheral neuropathy, if it was a new neurological process, or if it was a worsening from a pre-existing condition." Pet'r's Ex. 18. Dr. Tracy continued that "there is a logical sequence of cause and effect between [Petitioner's flu] vaccination he received on October 30, 2013 and his significant worsening immediately thereafter." *Id.*

Although Dr. Becker did not directly state that Petitioner's peripheral neuropathy predated his vaccination, the record contains compelling evidence that Dr. Becker believed that Petitioner has suffered from peripheral neuropathy since 2011. In addition to Dr. Becker's statement in his letter that Petitioner had progressive numbness in his arms, hands, and feet since 2011, in records dated September 1, 2015 and August 4, 2015, Dr. Becker wrote under "past medical/surgical history" that Petitioner had "[p]eripheral neuropathy since 2011[.]" Pet'r's Ex. 5 at 5, 10. Although these do not constitute contemporaneous medical records, "[m]edical records, in general, warrant consideration as trustworthy evidence." *Cucuras*, 933 F.2d at 1528. When viewed in combination with his letter, it is evident that Dr. Becker believed that Petitioner's peripheral neuropathy predated his vaccination.

Although Drs. Becker and Tracy have raised the possibility that Petitioner's vaccination may have aggravated a preexisting condition, Petitioner has not raised a significant aggravation claim. Despite several opportunities to amend his petition since he filed it in 2016, most notably after Drs. Becker and Tracy submitted their letters in February 2019, Petitioner has been steadfast in his refusal to do so. In fact, he has directly denied in filings that his peripheral neuropathy predated his vaccination. *See* Pet'r's Reply at 1. Moreover, Petitioner has not presented evidence or arguments pertaining to the *Loving* prongs. Specifically, Petitioner has not presented a medical theory that explains how a flu vaccine could significantly aggravate preexisting peripheral neuropathy pursuant to *Loving* prong four. Notwithstanding the opinions of Drs. Becker and Tracy, I will not decide a case that is not before me. *See Hirmiz v. Sec'y of Health & Hum. Servs.*, 119 Fed. Cl. 209, 220 (2014) (rejecting the petitioners' attempt to raise a significant aggravation claim after a special master issued an entitlement decision because the evidence "cited by petitioners that would support a significant-aggravation theory . . . was submitted in support of separate and distinct theories of causation[] . . . [that involved] neurological dysfunction beginning *after* the administration of the influenza vaccine[]") (emphasis in original). Petitioner has neither alleged that his vaccination significantly aggravated a preexisting injury nor presented evidence that could satisfy the *Loving* factors. Thus, I am evaluating this case as a causation-in-fact claim for a nonspecific neuropathy.

Based on the record in its entirety, I find that Petitioner has not shown by a preponderance of the evidence that his peripheral neuropathy arose after his vaccination. Because "the vaccine logically cannot have caused [a disorder that predated vaccination,]" *W.C.*, 704 F.3d at 1358, Petitioner has not satisfied prong two.

Even when affording due weight to the opinions of Petitioner's treating physicians, those opinions do not establish a causal relationship between Petitioner's vaccines and injuries. For the reasons explained above, Dr. Becker's opinion does not support that Petitioner's vaccination caused his injury. Dr. Tracy also indicates that Petitioner's peripheral neuropathy may have predated his vaccination. Furthermore, Dr. Tracy's claim of a probable association between Petitioner's vaccination and injury appears to be based solely on temporal proximity, which cannot alone support causation. Although Petitioner did not submit a letter from Dr. Nelson, the record indicates that Dr. Nelson communicated his belief that Petitioner's neuropathy was unrelated to his flu vaccination to Dr. Becker. *See* Pet'r's Ex. 5 at 40. Further, Dr. Kedl argues that the testing Dr. Nelson oversaw should give added weight to Dr. Nelson's opinions. Resp't's Ex. A at 8.

For the reasons set forth above, I find that Petitioner did not present preponderant evidence that his peripheral neuropathy was caused-in-fact by his flu vaccination. Thus, Petitioner has not satisfied *Althen* prong two.

3. *Althen* Prong Three

To satisfy the third *Althen* prong, a petitioner must establish a "proximate temporal relationship" between the vaccination and the alleged injury. *Althen*, 418 F.3d at 1281. This "requires preponderant proof that the onset of symptoms occurred within a timeframe for which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation-in-fact." *de Bazan v. Sec'y of Health & Hum. Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008). Typically, "a petitioner's failure to satisfy the proximate temporal relationship prong is due to the fact that onset was too late after the administration of a vaccine for the vaccine to be the cause." *Id.* However, "cases in which onset is too soon" also fail this prong; "in either case, the temporal relationship is not such that it is medically acceptable to conclude that the vaccination and the injury are causally linked." *Id.*; *see also Locane v. Sec'y of Health & Hum. Servs.*, 685 F.3d 1375, 1381 (Fed. Cir. 2012) ("[If] the illness was present before the vaccine was administered, logically, the vaccine could not have caused the illness.").

Although a temporal association alone is insufficient to establish causation, under the third prong of *Althen*, a petitioner must show that the timing of the injury fits with the causal theory. *See Althen*, 418 F.3d at 1278. The special master cannot infer causation from temporal proximity alone. *See Thibaudeau v. Sec'y of Health & Hum. Servs.*, 24 Cl. Ct. 400, 403–04 (1991); *see also Grant*, 956 F.2d at 1148 ("[T]he inoculation is not the cause of every event that occurs within the ten[-]day period . . . [w]ithout more, this proximate temporal relationship will not support a finding of causation." (quoting *Hasler v. United States*, 718 F.2d 202, 205 (6th Cir. 1983))).

Petitioner has not fulfilled the third prong. Petitioner's purported theory does not include a timeframe through which to determine that there is a proximate temporal relationship. Petitioner notes that "the Vaccine Injury Table recognizes a [three to forty-two] window for the onset of GBS post[flu] vaccination." Pet'r's Mot. at 20. However, Petitioner has not alleged, nor does the record support, that he suffered from GBS. He has not established why the GBS timetable is analogous to his case or how it could provide the basis for a temporal relationship here. Further, Petitioner has not demonstrated that the malaise he experienced within a week post vaccination is related to his peripheral neuropathy. Lastly, I have already determined that Petitioner has not established by a preponderance of the evidence that his peripheral neuropathy arose post vaccination.

VI. Conclusion

After a careful review of the record, Petitioner has failed to prove by preponderant evidence that his peripheral neuropathy was caused-in-fact by his October 29, 2013 flu vaccination. Accordingly, I have no choice but to **DENY** Petitioner's claim and **DISMISS** his petition.[101]

IT IS SO ORDERED.

[101] Pursuant to Vaccine Rule 11(a), entry of judgment is expedited by the parties' joint filing of a notice renouncing the right to seek review.

s/Herbrina D. Sanders
Herbrina D. Sanders
Special Master